This verbatim transcript of the WTC Health Program Scientific/Technical Advisory Committee, Committee Meeting held telephonically on March 28, 2012, has been reviewed for concerns under the Privacy Act (5 U.S.C. § 552a), and personally identifiable information has been redacted as necessary.

THE U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH

convenes

MEETING TWO

WORLD TRADE CENTER HEALTH PROGRAM

SCIENTIFIC/TECHNICAL ADVISORY COMMITTEE

VOL. II

DAY TWO

THURSDAY, FEBRUARY 16, 2012

Jacob K. Javits Federal Building
26 Federal Plaza New York, NY

Continuation of page numbers from previous meeting on 2/15/12

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The verbatim transcript of the

Meeting of the Scientific/Technical Advisory

Committee held at the Jacob K. Javits Federal

Building, New York, New York, on February 16, 2012.

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In the following transcript: a dash (--) indicates an unintentional or purposeful interruption of a sentence. An ellipsis (. . .) indicates halting speech or an unfinished sentence in dialogue or omission(s) of word(s) when reading written material.

-- (sic) denotes an incorrect usage or pronunciation of a word which is transcribed in its original form as reported.

-- (phonetically) indicates a phonetic spelling of the word if no confirmation of the correct spelling is available.

-- "uh-huh" represents an affirmative response, and "uh-uh" represents a negative response.

-- "*" denotes a spelling based on phonetics, without reference available.

-- (inaudible)/ (unintelligible) signifies speaker failure, usually failure to use a microphone.

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PROCEEDINGS

(8:36 a.m.)

COMMITTEE BUSINESS

DR. WARD: Okay, we're going to get started and call the meeting to order, starting with Paul doing the roll call.

DR. MIDDENDORF: If the members around the table would just state their name for the record, that would be great.

MS. HUGHES: Catherine McVay Hughes. Hello? Catherine Hughes.

DR. ROM: Bill Rom.

DR. QUINT: Julia Quint.

MS. MEJIA: Guillermina Mejia.

MS. SIDEL: Susan Sidel.

DR. WARD: Elizabeth Ward.

DR. HARRISON: Bob Harrison.

DR. ALDRICH: Tom Aldrich.

DR. TALASKA: Glenn Talaska.

DR. NORTH: Carol North.

DR. MARKOWITZ: Steven Markowitz. Steven Markowitz.

DR. MIDDENDORF: And then on the phone we have anyone?

DR. DEMENT (via telephone): John Dement.

DR. MIDDENDORF: I heard John Dement. Did I hear Virginia also?

DR. WEAVER (via telephone): Yes.

DR. MIDDENDORF: Okay. Thank you very much. Let me also point out since we're in a different room we do have different evacuation routes. The easiest way to get out of here is to go through the double center doors over here, to my left and in the back of the room, you go straight through the next set of glass doors and immediately turn to your left, and the fire exit is marked on a door down that hallway. In case we need to evacuate, that's where we need to go.

DR. WARD: Okay, so we have a short time before we start the public comments, and we'd like to ask Dori Reissman to speak to us about the question that was raised yesterday regarding the language in the Zadroga Act.

DR. REISSMAN: Good morning, everyone. So I'm Dori Reissman, I'm the medical director for the World Trade Center Health Program. And what I wanted to try and do for you was to clarify, I think, the questions that I heard yesterday regarding whether or not there are certain criteria that you need to meet within this committee in order to make a recommendation regarding cancer.

So what I wanted to clarify was that in the Zadroga legislation, the following quote is: World Trade Center-related health condition means a condition that is an illness

or health condition for which exposure to airborne toxins, any other hazard or any other adverse condition resulting from the September 11th terrorist attacks, based on an examination by a medical professional with experience in treating or diagnosing the health conditions included in the applicable list of the World Trade Center-related health conditions, is substantially likely -- this is the part that really should catch your ear -- is substantially likely to be a significant factor in aggravating, contributing to or causing the illness or health condition as determined.

Now what this means, that quote specifically refers to the job of the clinician in the program to individually assess somebody's exposure and disease relationship. It is not your charge. Your charge -- the only language actually in the statute about your charge had to do with the administrator's discretion to request input from you, advice from you, as to whether to include cancers or type of cancers in the list of covered conditions.

Once that list is established, which we already do have quite a number of conditions there, then the clinician within the program can assess the individual's exposure disease relationship for that individual's determination. Okay?

What the administrator asked you to do, and charged the committee very specifically, was to give him a scientific basis for your recommendation. That didn't restrict you to any definition of what the scientific basis meant. So I wanted to be very clear about that.

Yesterday I heard a variety of interpretations of what that could be. Some of it is reasonable, I think, was a word that you used. One of them was more likely than not. Whatever it is that you decide, you need to use those criteria along with how you're scientifically arriving at your recommendation. Does that answer the question?

DR. WARD: Are there any questions for Dori? Yes, Glenn. John, you have a question as well?

DR. DEMENT: I didn't check but I (indiscernible).

DR. TALASKA: So we can take -- from what you understand, then we can decide what level of recommendation to make to the administrator about the disorders that we're considering.

I just wanted to be absolutely clear. It's up to the committee then to set the strength of recommendation to the administrator as to what we feel is the relationship between the exposure and the disease then, right? And the condition?

DR. REISSMAN: Yes, you can comment on what you believe the strength to be.

DR. TALASKA: Yeah.

DR. REISSMAN: And if you feel that there are criteria that you'd like to see

continued to be used, you can make a statement about that as well.

DR. TALASKA: Gotcha, okay.

DR. REISSMAN: Do I need to repeat anything since this microphone was not on? Or are we good? Okay, thank you.

DR. WARD: Okay, so were there any questions from the committee members joining us by phone?

DR. WEAVER: So, we couldn't hear that, or at least I couldn't hear it.

DR. WARD: Okay, so we'll ask Dori to repeat that.

DR. MIDDENDORF: We don't have time.

DR. WARD: Well, we don't have time for the whole thing but maybe she'll give us a quick summary.

DR. REISSMAN: I'm sorry about that for the people on the phone, I thought it was on. The bottom line was yesterday in the meeting there was a question about a specific criterion for scientific relationship between a health condition and an exposure, and it was a specific quote of the health condition or the exposure is substantially likely to be a significant factor in aggravating, contributing to or causing the illness or health condition.

And what I was saying to the committee here was that that is for an individual clinical assessment of exposure disease relationships. That is not your charge. Your charge is simply to look at whether you think cancer or a type of cancer is appropriate to add to the list whereby a clinician can then apply that criteria of substantially likelihood test, if you will, to that individual clinical assessment. And the criteria that you can use are up to you; it could be more likely than not, it could be reasonable, it could be whatever words you choose but the advice that you give to the administrator needs to have a scientific basis and rationale.

PUBLIC COMMENTS

DR. WARD: Well, I'll turn it over to Paul for the public comment period.

DR. MIDDENDORF: Okay. Thank you. I want to point out that each of our commenters is signed up on a first-come first-serve basis, and each of them will have up to five minutes to present.

I want to remind our commenters that it's often surprising how quickly five minutes can go by when you're talking about a subject of great importance to you. So at four minutes I will let the commenter know that they have one minute remaining so they can make sure that they have the opportunity to make the most important points and make sure they get that across to the committee. If they have not finished at five minutes, I will have to rudely interrupt them and thank them for their comments. I apologize up front to anyone to whom that occurs but we must do that to be fair to all of our commenters.

We do have several commenters who are on the phone, and I just want to remind them that they should keep their phone on mute until I call their name. Then they should unmute and make their comments; and again, I will give them a warning when there's one minute left and let them know when their five minutes is ended. Also I want to point out to everyone that you do have the option of submitting written comments to the docket to this committee. The docket number is 248, and you can find the instructions on how to get to the docket in the Federal Register Notice, it's on our committee web page, it's also on the NIOSH docket page. Lastly, I want to remind our commenters about the redaction policy for public comments. That policy is also published in the Federal Register Notice; it is on the committee web page and also the registration in the back here, if you want to look at that.

So, with that we will go to our first commenter who is on the telephone, Jeffrey Stroehlein.

JEFFREY STROEHLEIN: Hello, I'm right here.

DR. MIDDENDORF: Okay, can you go ahead and start?

JEFFREY STROEHLEIN: Yes. I'm Jeff Stroehlein, retired New York City fireman, May 9, 2011. On September 11, 2001, the United States and the world was struck with an incredible, terrible tragedy. Two planes crashed into both towers of the World Trade Center. The loss of life on that day was incredible. It would affect the lives of many as the world watched in horror.

I'm here to represent firefighters and first responders with the after-effects of that day, the cancer that has followed in the 9/11 path. On March 16, 2011, my life was regular: go to work, hustle the kids around, pay bills, enjoy family life when time was available, as we both worked and tried to mix our schedules so we could have one of us with the kids and pass some length of times.

The problem was that for about ten to 14 days I was having headaches. I'm pretty tolerant of pain and not a guy who gets sick a lot. My wife had had enough and on March 17, St. Patrick's Day, earlier I was at the doctor's office. My wife then convinced the doctor to send me for an MRI. She's in the nursing field.

Later that day the doctor called and said he wanted to see us. My wife knew that wasn't good news and we headed right to North Shore Hospital.

The next day, March 18, 2011, I was in surgery getting a brain biopsy. Our world would change as I was diagnosed with large-mass brain lymphoma (indiscernible) CNS lymphoma.

My head had been cut open and I had ten staples in my head as I was medicated for pain. As I got my senses back and was given terrible news of my cancer diagnosis, I did not sit and cry and feel sorry for myself. The first thing I told my

wife was I will not lose to cancer. Then for my three children and my little girl who turned four the next day on March 19th, I would not be there to celebrate as I lay in the hospital bed. This was just a start as we decided to transfer to Sloan-Kettering Hospital.

It was in that time there was much to do in case the worst would happen and I was to pass on. We needed a healthcare proxy, a will and a power of attorney. But when (indiscernible) support there was absolutely no help from FDNY as far as what to do. It felt like our world had just been turned upside-down. I would not lose any of my spirit as I would fight the fight. I would stay positive through all my chemo treatments, and I have no plans of anything different. The side effects have been no bargain. As much as I have told you about me, this isn't about me; it's about us, the first responders, who are still being diagnosed with cancer ten and a half years later. I am the voice for all first responders.

FDNY doctor, **[identifying information redacted]**, did a study the first seven years after 9/11 and cancer was at 19-percent higher rate in (indiscernible) responders than those who weren't there. That's just firemen.

I was diagnosed in the ninth year after 9/11 and still hear of first responders being diagnosed with cancer every week. My stats and others are not even in the 19-percent stat. The percentage is higher than that and still growing. Although sad, there will be more first responders diagnosed with cancer.

All FDNY vehicles that responded to 9/11 were loaded with dust and debris. They all went back to their firehouses uncleaned. Now the firehouse was contaminated. Where was a fireman's gear after his day on the Pile? Uncleaned and back in the firehouse.

Ten and a half years ago -- I'm sorry, all FDNY members were ordered on the chart down to the pit and clean-up. There were so many contaminants, poisons in the air, two airplanes disappeared, glass, computers, desks, jet fuel and even human body parts were in the air that day for months and who knows how long after. As my friend **[identifying information redacted]**would say, for any of those toxins individually in a bottle, and it would have a skull and crossbones, with a do not inhale. These were many unknown amount of toxins. In the early stages the city was unprepared with little paper painting sheetrock masks. Twenty minutes of breathing and moisture, and the mask would be torn open over your mouth. Later we were told the air was safe to breathe. Why would you give out masks if the air was safe to breathe? Many lung and breathing problems have occurred. Many in first responders. How is cancer not caused? Are the people who make this decision blind? None of them were on the Pile, no politicians were digging on the Pile.

Ten and a half years ago, FDNY, police officers and all the first responders were getting pats on the back and 'atta-boys as politicians praised them. They couldn't do enough for them.

DR. MIDDENDORF: One minute, please.

JEFFREY STROEHLEIN: Now you can turn your back and deny, deny, deny. Cancer cannot be caused from all these toxins of 9/11? There is no doubt cancer was in the air on 9/11. I speak for all first responders but mostly FDNY as that's where I worked. As more and more first responders die of cancer every week, something must be done. I will not be one of the first responders who loses his fight with cancer. Thanks for all my support and my wife, my family's, and to (indiscernible) 162, many other firehouses and the FDNY and all my friends. I'll be here fighting the fight. God bless.

DR. MIDDENDORF: Thank you, Mr. Stroehlein.

Our next commenter is Jim Melius.

DR. JIM MELIUS: Mic working okay? I have a head cold, my ears are plugged up so hard to tell. Anyway, good morning everybody on the panel, everybody here. I'd like to thank Dori who saved me about three minutes by going over some of the same territory and now I don't have to go into long definitions as much.

What I'd like to comment on this morning is what your task is here, and I think it's very important to recognize it's not the usual review of a carcinogen, what would be done by IARC or NTP or some regulatory agency. Rather, you're being asked to make a determination whether a medical condition should be added to the list of World Trade Center medical conditions.

That list is going to be used to determine whether or not people in this program will be treated for that medical condition, but only after a physician determines that that patient has that condition, the definition that -- criteria that Dr. Reissman just spelled out, and that that condition for that particular patient is World Trade Center-related. And even after that physician makes that determination, that will then be reviewed by someone at NIOSH and following a, you know, some sort of a standard pattern of criteria so there's -- there will be consistency in that certification process.

And this kind of setup was deliberately put in place in the legislation, this sort of two-step process: one, there would be a list of medical conditions; secondly, there would then be an application of a physician diagnosis determining whether or not for that particular patient, their condition was related to their World Trade Center exposures.

Because, and I think it's sort of obvious that you cannot expect a panel such as yours to make a determination for every single person, every single circumstances.

This is a complicated situation, you're going to be look at -- you covered much of this yesterday that came up; it's a complex exposure, many carcinogens in it, it's not very well documented in terms of levels of exposure, many different types of work that went on. There's a high rate of respiratory and other illnesses that don't really track with the exposure measurements that were made, at least quantitatively. You have a limited time of follow-up so a full determination on what will be the disease experience for this population will go on for many years, 20, 30 years.

However, you know, Congress didn't ask -- expect you or the administrator to wait 20 or 30 years. They actually asked for an annual review of whether or not cancer was a World Trade Center-related condition and a determination and a report to be made on that by the administrator. And I think it's -- as you look at this evidence and make your scientific and medical evaluation of that evidence, I think it's important to put that in that context. You're making a determination on really whether or not a condition'll be covered for medical treatment in this program. And I think as we heard yesterday, we'll probably hear more tomorrow, that determination has significant consequences for the people in the program. We don't have a perfect healthcare system and as all of us -- you know, and many of you experience daily is that coverage is limited for many people, and there's an economic and personal hardship for people if this isn't covered. And that that should be -- the context should be simply is this -- should this be added? Should there be coverage provided given the process that's in place.

I think it's obvious you shouldn't -- you know, you're not going to be adding a condition that it's not possible for a physician to make that determination based on the evidence or something, so there's some rationale to it.

DR. MIDDENDORF: One minute.

DR. JIM MELIUS: I know I have one minute, yeah, to go, but at the same time I think it's a much different level of evidence than you would require for a IARC carcinogen or whatever, and it's hard; it's even hard for me, I know, thinking about this, I think possible-probable, I can of certain types of evidence. You know, and so forth that I think you have to think about this and approach this differently.

Finally just briefly I want to say one piece of advice I think -- and I appreciate the public comment period, I appreciate you adding more time. I think we're hoping for next time to be able to have some more convenient times for people coming in. The committee that I chair we do -- we allow people ten minutes, and we do that and, you know, sometimes people go on long but it's not for people like me 'cause I can probably try to tighten up what I say and get it in five minutes, but for the people that are affected by the program they need -- they really do, many of them

do need more time to explain. They don't know what you're looking for and it really does help them. And I'll end there.

DR. MIDDENDORF: Thank you very much. Our next commenter will be Michael Barasch.

MICHAEL BARASCH: Good morning everybody and thank you for the opportunity to speak this morning, and thank you for your time and volunteering on this committee. I'm an attorney and I'm with the firm of Barasch and McGarry. I'm proud to say that my firm represented Jimmy Zadroga, and we currently represent his little daughter and father. We've represented thousands of rescue workers at the first victim compensation fund in the subsequent years after, and currently thousands who are now in treatment and hoping to apply to the new victim compensation fund.

I'm very familiar with the respiratory illnesses sustained by the Ground Zero workers and for better or worse I get calls every day from guys and women afflicted with cancer.

This morning I have brought with me three of my clients. They have asked me to speak on their behalf. First, **[identifying information redacted]**, would you stand up, please? **[identifying information redacted]**. On September 11th John was 44 years old, living in Staten Island and an active member of the Ladder 103 in Brooklyn. He responded to the attacks and worked over 300 hours on the Pile. His boat from Staten Island that morning was one of the first to arrive as the towers fell. His group of firefighters dug out **[identifying information redacted]**, who was one of the few to survive the buildings' collapses.

Prior to September 11th John was very healthy and a nonsmoker. He currently suffers from chronic bronchitis, chronic cough and last September -- I'm sorry, September of 2010, he was diagnosed with non-Hodgkin's lymphoma.

He wants me to say that the cancer has taken an enormous psychological toll on his wife, his 11- and 13-year-old daughters, who have watched him sick and go through chemo. He's most scared of course of not knowing whether he'll be there to see his daughters grow up.

He wants you to know that notwithstanding his illness he's proud of his service and would do it all over again.

[identifying information redacted]. [identifying information redacted]? On September 11th, **[identifying information redacted]**was 47 years old and had retired three months beforehand. He had worked for the FDNY Engine 23 in Midtown. Selflessly he responded to the attacks before the first building collapsed, and he worked hundreds of hours at the Pile.

He's currently suffering severe reflux and leukemia and being treated at

Sloan-Kettering. Prior to September 11th, he was very healthy and a nonsmoker. He has a wife and two daughters, and he wants you to know that he, too, would do it all over again.

And **[identifying information redacted]**. On September 11th, **[identifying information redacted]**was 43 years old and an active member of Ladder 172 in Brooklyn. He responded to the attacks and worked 45 days on the Pile. Last year **[identifying information redacted]**was diagnosed with lung cancer. Recently he was devastated by the news that the cancer has spread to his brain and his spine. He knows that the chances of him being alive in five years are less than two percent, and prior to September 11th, he was a healthy individual and a nonsmoker.

Look, we all recognize that the risk of adding cancers to the victim compensation fund and to the treatment program are real. It will reduce the money available for care, treatment and compensation available to those who are suffering from respiratory illnesses which are already accepted as illnesses caused by the Trade Center dust. On the other hand, to wait another five years for indisputable proof of causal connection means that many of the rescue workers in this room or listening from their offices and homes, will not live to see the benefit of what seems to be a foregone and logical conclusion. With all due respect, I'd like to suggest that this committee accept what some of the experts, such as **[identifying information redacted]**and Prezant have opined. To wit, there is a high degree of certain that toxic dust exposure has and/or will cause cancer.

DR. MIDDENDORF: One minute, please.

MICHAEL BARASCH: I submit that at this time, at least for the rescue workers who were on the Pile, you should recommend immediately that the respiratory cancers, esophageal cancer, the blood cancers, thyroid and prostate cancers be recognized as being caused by the toxic World Trade Center exposures. Thank you.

DR. MIDDENDORF: Thank you very much. Ask our next commenter to come up, David Howley.

DAVID HOWLEY: That's an act to follow, good lord. Okay. Well, I'm going to be, I guess, the first police officer; I mean, everybody else was a fireman. Good morning, everybody. My name is David Howley, and I'm retired from the New York City Police Department.

A lot of this stuff is covered so I'm not going to try to make you hear all the same things, you know, two and three and four times, however many times people speak today. So I'm going to try to make this personal for you guys at your level, what you guys have to think about.

So the first thing is just real briefly about me. In 2006 after retiring, I was diagnosed with squamous cell, head and neck cancer. From that point on, first

oncologist told me basically I was dead and didn't know enough to die yet, and that's a true statement and you can look at my wife's face back there and I'm sure it's registering horror. The next doctor wanted to, because they didn't know where the primary was, because squamous cell only shows up with PET scans, they didn't know where the primary was; they couldn't find it. So next doctor wanted to cut me up into little pieces to try to find, and do biopsies everywhere, to try to find where this thing was 'cause it didn't show up. I've had two strokes and I was overdosed on chemotherapy once and almost died from that, too. Basically my doctors now call me the miracle patient 'cause none of them thought I'd be here. So, okay, well, I am and we're moving forward and we go from here. So let's put this in your guys' ballpark. You guys have been given a responsibility that should never have been put in your doorstep in the first place. There's no question about that. Cancer should have been in the original law. Congress people were told it should have been put in the original law, and they refused to do it. Why? God only knows about that one. But so here you are.

So you have to make the determination not only about the facts that are in front of you, which as the good lawyer said, you can't do with a hundred percent certainty because this kind of stuff, and a lot of you I know are doctors and researchers, and you're used to dealing with long studies and drawn out, clean sterile environments, you guys are used to working with them. Many of you are that I know. You don't have that here. You're not going to have that here; it's never going to happen, because the disaster itself was at such magnitude that there's nothing for you folks to compare it to. This is all brand new. Nothing of this size, scope, amount of concrete, glass, steel, toxins, dust, office equipment and everything else has never -- then burned at 3,000 degrees, has ever happened before in the history of mankind. So you can't go back and go, well, this happened in 1924. It's relatively close, let's compare and see what happened to those people. It was -- there's nothing to compare it to.

Our grandchildren, if we're lucky enough to have grandchildren, will wind up doing thesises (sic) on their own when they're going to medical school, and try to put all this together for us. And they may still not have 100-percent concrete answer. It's that, it's that bizarre what happened that day.

So you have to look at it as well, what's the best possible evidence that you have? What seems to be what's going to happen? So you really, the only wrong decision, as far as I can tell, I think it's pretty much a ground ball, is to go -- is to not do this. Because by not doing it, you're going to be slowing down the research or stopping the research; you're going to be stopping people from getting the treatments that they deserve, you're going to be stopping the families from getting the support that

they needed. And you also quite frankly have to be able to look in the mirror for yourselves and go, you know what, did I maybe not save somebody's life today or this person down the road and maybe today, maybe tomorrow may have died because they weren't able to get the treatment that they need.

I was very lucky, I had a great support system that I was able to get it, and I still went through hell. But I'm here. Other people might not be that lucky.

And last but not least, so I don't take up too much of your time, you guys also unfortunately have to look down the road. What if this hap -- we're basically fighting a world war. We're in the middle of a world war. We don't call it that but, being politically correct as we are this day we probably wouldn't, but if this was the 1940s, this would be considered a world war. And we're still there today. And you guys have to look and go, if this happens again, are those same first responders, guys like me, guys like these three firemen, guys like the fireman on the phone, are we going to go down there? Are the guys and girls that are out there on the street today gonna go down there and do the same thing? Ninety-eight percent of the people that were below the floors where the planes struck got out of that building alive. Will that happen again? It rests on your shoulders. Thank you very much and God bless you.

DR. MIDDENDORF: Thank you very much, Mr. Howley. Our next commenter is Michael Winter.

MICHAEL WINTER: Good morning. This is extremely difficult for me so I apologize in advance. I've been affected by post traumatic stress disorder due to September 11th.

On September 11th I was in charge of the operations control center at United Airlines. I was in the job to manage the people who were legally responsible, along with the captain, for every flight operated by that airline and every airline in this country. Every flight operated by U.S. airlines is required to have a licensed aircraft dispatcher managing the flight on the ground along with the captain in the air. The reason dispatcher is highly trained and licensed is they have to know the same thing as the airline captain does. Dispatchers take their job very seriously. I took the job of managing aircraft dispatchers for United Airlines very seriously.

Like most people I remember seeing the pictures of the hole in the side of the first twin tower hit. I knew it was not a small aircraft as they had reported on my commute to work on the radio.

I can still feel the impact of the second tower on my body as I stood and watched it on the overhead screen in the ops control center. There have been many times I wish I would have died on that day. It would have stopped the pain, the feeling of responsibility, the never-ending questioning of what we could have done

differently, what could we have said differently for the flight attendant that called from the back of Flight 93, telling us that the aircraft was in control of hijackers. The emotional numbness I feel while trying to be a good husband and father. The difficulty being with other people, the total loss of interest in doing things I used to enjoy. The nightmares and sleepless nights are too numerous to count anymore. Fortunately a small piece of me still wants to live and make a difference in the world. My therapists say it is possible for people with PTSD to recover to a point where they can function in the world but not without consistent treatment. I've had to pay for the treatment thus far out of my own pocket, as my wife's insurance plan does not cover mental health for family members.

I just want to read a couple excerpts from summaries written by my therapist and by the MD that diagnosed me with post-traumatic stress disorder. Michael Winter first presented with his wife, **[identifying information redacted]**, for family therapy on 1/15/2009; primarily presenting issue was children's symptoms. Secondary issues reported by **[identifying information redacted]** were multiple family problems related to changes in Michael's behavior that began in 2001 and continue to present. Michael's behavior changes that affected work relationships and lifestyle. Michael had moved upward in his career until he reached a career path in April 2001, when he became the head of the flight dispatcher organization for United Airlines, overseeing approximately 300 employees. As a flight dispatch manager, Michael was present on the flight control floor and directly supervised the flight dispatcher who monitored two of the flights that were crashed by the terrorists on September 11th. During the hours that followed the first plane crash, Michael was at the center of United Airlines' response to the terrorist take-over of aircrafts. He encouraged the supervisors to get flights safely landed, helped draft a message to the flight crews in the air, warning of possible terrorist attacks.

By the way, the message from **[identifying information redacted]** to Flight 23 leaving JFK with six terrorists on the airplane was stopped before it got off the ground. Our messages were sent prior to anybody in the air traffic control system, and we stopped that flight from taking off. Michael was at his post helping to bring home the surviving planes and doing damage control for the company hit hard by terrorist attacks.

He continued to work for United Airlines, following 9/11 and initially responsible for reorganization and down-sizing directly related to 9/11. Gradually he was demoted until he resigned after sick leave was exhausted. **[identifying information redacted]** reported that the marriage had been very satisfying and life had been good up until then but constant changes in mood and the ability to deal without anyone locking himself in a room for days.

Michael's presenting symptoms include irritability, physically withdrawing from the outside world, lack of joy in daily living, panic attacks, moodiness, constant vigilance, emotionally withdrawing from his wife and children, avoidance of discussions involving 9/11, emotional numbing, memories intrusive sleep.

One other just comment -- well, actually this is the end of her letter. It says in my opinion that Michael Winter continues to suffer PTSD symptoms that are directly related to the events of his professional position responsibilities with the aircraft that were hijacked on that day. Michael was indeed a first responder on that date and a professional who stayed on duty to begin the remaining, the remaining airplanes home safely.

DR. MIDDENDORF: One minute, please.

MICHAEL WINTER: One minute? My final comment will be --

MATTHEW MCCAULEY: Mr. Moderator, I have -- I'm up next; I cede two minutes of my time to Mr. Winter.

DR. MIDDENDORF: No, you cannot cede.

MATTHEW MCCAULEY: Okay.

MICHAEL WINTER: Thank you. People on the ground that had not been directly involved in the terrorist attacks on that day are covered for PTSD, and my request is I be covered or just treated as a first responder. All I'm asking for is health benefits to get me back to living at least a somewhat normal life.

I'm lucky to be here. A lot of people as you know, don't make it through severe PTSD; they end up killing themselves because the pain is just too great. I know that a lot of people, you know, certainly the people that are there have been hurt, and I understand that, but I'm just asking for some compensation ben -- just for benefits and health benefits, not compensation.

DR. MIDDENDORF: Thank you very much. I do want to point out to our commenters that if there are additional -- there is additional information that you're able to present here while you're giving your public testimony, you do have the option of submitting to the docket, and any of the comments that come into the docket are shared with each of the members of the committee. So that's another way that you can get your information to the committee. Our next commenter is Matthew McCauley.

MATTHEW MCCAULEY: Good morning, ladies and gentlemen. Thank you for permitting me to address this panel. My name is Matthew McCauley. I'm an attorney with the law firm of Parker and Waichman, and we represent numerous health -- numerous first responders, many of whom suffer from cancer. Wasn't always a lawyer and I won't always be a lawyer. I started out as a New York City police officer and I will always be known as being retired from the job. I've also

been a paramedic for over 20 years, and it's what drives me to see through my clients' eyes because I was a first responder at the 1993 and at 2001 terrorist attacks. I'm one of the few attorneys you can say that they've seen the same things through their clients' eyes, as many of them have served beside me and also beyond me, beyond my days at the World Trade Center.

I come here to ask you to support the suggestion that at least certain cancers make it into the fund and for healthcare benefits. As you heard over the last two days, a lot of statistical issues that are there, trying to evaluate whether or not there have been reported cases or non-reported cases. Three people -- two people you heard from are out of state: **[identifying information redacted]** in North Carolina and **[identifying information redacted]** who came up from Chicago.

There are many others like them that I also represent, who have cancer. They're not counted because they came in from out of state, whether they be a member of a USAR team in Florida or Chicago or if they came in from Pennsylvania. If they fell outside the bell curve when the first reports came in and they're not part of organized labor, whether it be NYPD, FDNY or their brother and sister labor unions, many of them have fallen through the cracks because they went home. They came here to New York, they did their job, they supported everybody, and now they have cancer.

They went on about their lives, they continue to go on about their lives, but many of them need the healthcare benefits and the compensation that goes along with including this.

They should not be forgotten and I am here today because I represent many of them, some from California, some from Florida, some from Chicago. They were not part of the people who were accounted for. **[identifying information redacted]**, who testified yesterday, is not in the World Trade Center (unintelligible) fund because he has cancer. He was not counted.

He tried to contact them a few years back, they didn't take his information because he wasn't having any qualifying injury. **[identifying information redacted]** is the same way. **[identifying information redacted]** in Florida, USAR team, same way. These are gentlemen who didn't come in with thousands, they came in one out of seven, one out of ten, two out of eight. Small numbers of people who came in from fire departments, police departments and first responders from around the country to help us. They're not part of thousands of people. You know, they came in in small groups and yet their small groups have been affected, and they're not spoken for.

With that extent, I work in a world of data and Daubert and all these other standards when it comes to epidemiology, and epidemiology is a lot of things, but for epidemiology, as you all know, you need to have good studies, good bases,

good ideas that go behind them. The problem was that there's a lot of different conflicts that are there. And we have issues as to whether or not we'll ever have a substantial amount of epidemiology. But the one thing that I think the researchers on this board know is that absence of evidence is not evidence of absence. And it should go forward. There's enough support out there for it, there's enough information out there for it.

We could never conduct a study with all of these toxins put together. There would be no reason to and a study to mash everything together as far as one that has never been done and likely can never be done in that setting.

Please look to the people who were not accounted for. Similar to the way adverse events are looked at from drug companies, it's those that are not counted that are the most important. Underreporting is pervasive here.

I've also come in support of Michael Winter. Michael is an outlier. Michael's here looking for healthcare benefits. He is somebody who absolutely was involved in protecting the skies over everybody's head. He was absolutely involved in the actions that took place at the World Trade Center, at the Pentagon and at Shanksville. He should not be denied medical benefits because he wasn't physically within the confines.

DR. MIDDENDORF: One minute.

MATTHEW MCCAULEY: Okay. He was not --

DR. MIDDENDORF: Also please try to speak in the microphone.

MATTHEW MCCAULEY: He was not physically within the confines of what is defined there. He was there. He was at every single one of those locations, and I think that every fireman, every police officer who was on the ground the moments after it happened will tell you that they looked up 'cause they were afraid. He was one of the people protecting them from above. He was one of the people clearing the air space. Do not leave him out. He should not be left out because a spectator -- sorry, a bystander who was in the Millennium Hotel, who was looking out the window and unfortunately may have PTSD, that person's qualified, that person is qualified. They were evacuated from the hotel, they left the scene. I feel sorry for that person, I really do, but Michael Winter is somebody who was involved in this. He does not fall under the guidelines of an exact first responder, that we all consider a first responder; he was there.

I just ask that you please include cancer into the qualified injuries and that there be some sort of mechanism to include the exceptional special circumstances like people like Michael Winter. Thank you very much.

DR. MIDDENDORF: Thank you, Mr. McCauley. Our next commenter is, excuse me, on the telephone, John Fassari. Are you there, Mr. Fassari?

JOHN FASSARI: Yes.
DR. MIDDENDORF: Okay. Go ahead and please begin.
JOHN FASSARI: Good morning. Thank you for taking my call. My name is John Fassari. I am a retired lieutenant from the New York City Fire Department. Operated at 9/11 for months, and I have to tell you that I have non-Hodgkin's lymphoma, a terminal cancer, something rare but also something that many of my fellow coworkers have gotten since operating at 9/11. And I just think that you need to hear that all of us, and many of my coworkers and friends that are not here today to make a telephone call or respond to this hearing because of the sicknesses and cancer that they had gotten and are no longer here.
I myself being somewhat lucky and still being here, I'm just only waiting now for the axe to drop. But I just had to respond to this and, you know, let anyone that is going to make this decision about cancer that I just can't tell you how many of my coworkers, friends and first responders have gotten sick.
Now, not only is it, you know, cancer and post-traumatic stress and all those other disorders that go with being sick, you know, it's a terrible thing, and I hope they reconsider and add cancers to the Zadroga Bill.
I know many families are looking for help and need help, and I hope in the future, and I hope that this conference will be strong enough to make the decision to help these families in need. And again, especially for the families that have, you know, lost their first responders, their dads, their moms, anybody else that operated there and is no longer there today.
New York City Fire Department chief medical officers believe that cancer is a big part of these guys being sick and I just wanted to let you know that, you know, we're sick and we're hanging in there. Thank you.
DR. MIDDENDORF: Thank you very much, Mr. Fassari. Our next commenter is Frank Tramontano.
FRANK TRAMONTANO: Good morning. My name is Frank Tramontano; I'm the research director for the New York City Patrolmen's Benevolence Association. Now more than ten years after the attack on the World Trade Center, this committee is searching for medical and scientific evidence to determine if cancer should be added as a covered illness for treatment under the James Zadroga Act.
There has only been one cancer study published to date, and other than some of the testimony heard here yesterday, there are no studies that analyzed the effect of the World Trade Center dust that was inhaled and ingested and its connection to cancers.
The testimony yesterday also revealed that there were no samples taken of the air for the first four days after the attack. So this committee has to decide on a cancer

petition with less than perfect information. There should have been more cancer studies and those that are about to come out, like the one **[identifying information redacted]** testified to this committee yesterday, has serious limitations.

It is mind boggling to me that the City of New York has not done more with the information they had regarding New York City police officers. On March 30, 2007, **[identifying information redacted]**, the then chief of staff of New York City deputy mayor, **[identifying information redacted]**, testified, and I quote, that the New York City Police Department did a particularly thorough job identifying who from their ranks responded to 9/11 or took part in the recovery and cleanup at the World Trade Center site.

Until yesterday, after days of getting beat up on this issue in the press, the City has finally agreed to release the data to Mt. Sinai. This is after denying them the information months earlier. If the City wanted to, we could have applied for research funds from NIOSH and hired staff and conducted an NYPD cancer study of its own. It is quite surprising this was not done, knowing that the City is constantly searching for ways to get more federal money.

The City has also failed to release its department of health cancer registry report. The report is not only late but it will also be severely limited since it has been closed to new registrants since 2004, and contains, according to our sources, only approximately 4,000 police officers. There were six to seven times that number of police officers who responded to the 9/11 rescue and recovery effort and were exposed to the horrific environmental conditions in and around Ground Zero.

Sadly the City of New York is not alone in its failures toward the 9/11 responders. The cancer study being released by -- shortly by Mt. Sinai Medical Center, which was briefly summarized yesterday by **[identifying information redacted]**, includes only those responders who are registered with the World Trade Center medical monitoring program, a program that doesn't treat cancer. We know of at least 70 police officers with cancer who should be in that study but are not.

As mentioned, there has been one study released on this issue. The past fall, the fire department published a study entitled, "Early Assessment of Cancer Outcomes in New York City Firefighters after the 9/11 Attacks." While that study demonstrated an increase in cancer rates among firefighter first responders, the study included an adjustment in the data to delay the date of diagnosis by two years. When taking this adjustment into account, the study would cover a period up until 2006, resulting in a period of time after the study being longer than the period actually covered by the study. Frankly I don't understand why this committee does not have an updated analysis from the fire department. It seems to me it would qualify as medical evidence.

As you know, the report did show a 32-percent higher cancer incident among exposed firefighters when compared to non-exposed firefighters before the adjustment.

DR. MIDDENDORF: One minute.

FRANK TRAMONTANO: The study also demonstrated an increase in incident of cancer for a later period after 9/11 when compared to a period immediately after the attacks, a trend that is likely to continue.

These are significant facts and along with some of the presentations yesterday represent scientific evidence that should be sufficient for this committee to support the addition of cancer as a covered illness. It clearly represents a higher evidence threshold than some other illnesses covered under the Zadroga Act.

But there is more evidence out there. Through the PBA's own cancer registry, we have recorded four nasal cancers when the annual rate of nasal cancer in New York State is .1 for every 100,000. There are approximately 30,000 police officers who filed a notice of participation with New York State, saying they worked at Ground Zero. The police pension fund has seen a rate of increase of more than three times the cancer accident disability applications since 2006. There would be more evidence to the City if others had done a better effort, but unfortunately they failed to do so.

Please do not make the responders with cancer suffer any more because of the lack of effort.

Finally I believe this committee must consider the financial implications of not recommending cancer. If you are like me and others in this room, and believe that there is just a matter of time before the scientific evidence unequivocally proves the cancer link for the sake of the financial implications or for the families of these responders, I beg you to recommend adding cancer as a covered illness.

In the end the treatment for this disease bankrupts families, even those with good medical plans. There are yearly medical spending caps and lifetime medical spending caps that for the responders -- for those responders that are lucky to survive with this disease wind up depleting their family assets. How can we in good conscience --

DR. MIDDENDORF: Your time is up.

FRANK TRAMONTANO: -- hesitate another day to add cancer to this list of illnesses when these selfless individuals do not hesitate a moment to the call of their duty. Thank you.

DR. MIDDENDORF: Thank you. Our next commenter is Keith LeBow.

KEITH LEBOW: Good morning ladies and gentlemen of the panel. My name is Keith LeBow. I am a sick World Trade Center first responder but I'm not here about

what's wrong with me today. I'm here to address the issue at hand, which is to add cancer to this act that we fought for. Excuse me.

Everyone knows and understands now that the dust of Ground Zero was toxic and contained many, many cancer-causing materials. Among them asbestos, hexavalent chromium 6, mercury and cadmium. These are not only cancer-causing but mutagenic as well, which means the cancer will be passed to future generations to come, mutating or changing as each new generation is born. Studies have been done, published but yet the fact of the matter is they are not being released to the people who need them the most.

The doctors who are working to figure out ways not to just deal with that, with what is wrong, but to heal us in the best ways that they can. Excuse me. Studies are fine for gathering data but to ignore the problem means that all the data in the world that you collect is worthless unless put to a good use. Now what I have right here in front of me is just a sample of what I was able to find online about this particular issue. To me that's great. It means to use this data means to save lives. That's the best thing in the world. We just need to -- you know, we just need better medical treatment.

What will it take to accept the fact that we were subjected to a very toxic environment with little or no protection at all? More deaths from various cancers? Cancers that normally take 20 to 30 years to manifest themselves are wiping out and have taken many people's lives in less than ten years. Many people need this to be added, especially people like construction workers who, unless they work, do not get paid, do not get benefits and have no way of paying for any of their treatments. To deny them this coverage means that once they are found to have cancer from the dust, must continue to work even though they are in dire need of this treatment; otherwise they must face mounting medical debt because they have no coverage. You don't work, you don't get paid, you are no longer covered. To ignore the obvious is to condemn many to horrible deaths.

Just imagine one day you wake up to find out yourself, your loved one or someone close to you has gotten cancer from breathing in toxic fumes at work. The doctors, as well as many others, know what caused them to develop cancer, but you were told that the studies must be done than to hear you were denied any kind of help necessary to help them.

You would want to move heaven and earth to do everything you could to save them, not only to have your pleas fall on deaf ears but just be denied completely. That is what is being done to us now.

So please, for the sake of sick and dying World Trade Center responders, victims, survivors and their families, please accept cancer as being a part of the Zadroga Act

so more do not pass on from it. Thank you very much for your time.

DR. MIDDENDORF: Thank you very much, Mr. LeBow. Our next commenter will be Tracy Conte.

TRACY CONTE: Good morning. My name is Tracy Conte and I am the daughter of retired FDNY Lieutenant **[identifying information redacted]**. My father worked at the Trade Center site for 16 consecutive days, sleeping inside of a body bag for a few hours at a time to escape the choking dust. He passed away on July 20, 2010, of the most aggressive case of metastasized prostate cancer that the oncologists and hematologists who treated him had ever seen in the history of their practice.

My father, Lieutenant **[identifying information redacted]**, developed the Trade Center cough right away and the lung issues. But there was no signs of cancer.

He remained active -- he retired in 2002 but remained healthy and active throughout his retirement, participating in his community, bringing a Memorial Day parade to his town after a 30-year hiatus, revitalizing the membership of his local American Legion, taking care of his grandchildren, taking care of his elderly neighbors.

On Memorial Day 2010, my father started experiencing back pain and difficulty breathing, and felt weak. By early July he was diagnosed with prostate cancer. Just five weeks after his symptoms appeared, he had lost 30 pounds, could barely walk and barely breathe. He entered the hospital on July 8, 2010, and what happened over the next 12 days was mind-numbing, like a freight train running out of control. His body stopped manufacturing blood, he received platelets and blood transfusion and still his blood oxygen level was dropping. The doctors could not figure out what to make of his advanced breathing difficulties and how his oxygen levels were dropping. They were scratching their heads, an entire team of doctors, all specialties.

A bone marrow biopsy uncovered that his marrow had been replaced by bad cells. The sample extracted during the biopsy was dust. His PSA score nearly doubled every 24 hours. Five days before he died it was 300. Four days before he died it was over 500. The day he died it was over 3,000 which was the highest score the doctors had ever seen.

Doctor after doctor told us that he was one of the sickest, if not the sickest, patient they had ever encountered in their careers. Every major system failed at the same time: lung, bone marrow, kidney, renal, heart. According to the doctors it was as though the cancer had bloomed throughout his body.

He had no family history, was the most aggressive case and was -- he was the sickest person that the doctors had treated and the doctors were scratching their heads. They had never seen anything like it. It was like a force had taken over.

The greatest human risk of exposure to the environment comes through our lungs, and if there is a shadow of question and an ounce of inconclusive evidence, then the commission needs to do the right thing. Cancer needs to be included in this bill, and I don't know why any compassionate person would choose not to. My family suffered the premature and sudden loss of a loving husband, father, grandfather, a man who always gave to his family, his community, the FDNY, the citizens, not only of New York City but anywhere he went, and his gift to all of you was that he risked his life every day to save yours, not just when he was at work but every living day. And just as every first responder does.

To exclude an entire group of people, people who showed up to help, based on a technicality that they didn't have the good fortune to come down with the right illness related to the World Trade Center would just be a sin. I urge you to reflect upon the choice that you make here and to include cancer in this bill. The amount of funds that have been allocated is the amount of funds. That will not change. So do the right thing, please, and that is to include cancer in this bill. Thank you.

DR. MIDDENDORF: Thank you very much. Our next commenter is Collin Ecosta (ph). Mr. Ecosta, are you on the phone per chance?

(no response)

Okay. If he happens to come in, we have a little bit of time at the end, we can move him to that time period. We'll move on then, and the next person is Mr. Alonzo Harris.

ALONZO HARRIS: Good morning everyone. My name is Police Officer Alonzo Harris. I was a first responder on 9/11.

Today I want to take you back to 9/11 and what it was like. I was a first responder when the plane hit on the building -- hit the first building. I also was there when a plane hit the second building. After being tumbled and buried under a car, I made my way back to my precinct and then I was taken to Bellevue Hospital. But the reason I'm here today is I wanted to express and show the panel what it was like. I have something very significant today for all of the thousands of first responders that responded here, and this is the uniform that has been tested by **[identifying information redacted]** who yesterday was here and he showed you some examples, I would like to bring out the uniform. I don't want nobody to get scared of anything; it's sealed. But I just want you to know what it is like for the first responders, the firemen, the policemen, all the city workers who was down there, what they accept and this is what it is. This is what they exposed to.

When I got home on that tragic night, I just sat back, my body was full of -- it was like I was full of an electric person 'cause when the building, the second tower came down, my whole body was just electric. So I said, you know, this is not good.

Let me put this uniform up. I put it in the bottom of my closet and I was going to put a harsh memory, a damp, damp, memory away. And I stayed home for like a week and a half.

After several years, one of my good partners, her name was **[identifying information redacted]**, she worked in PSA 5, she succumbed to cancer at Sloan-Kettering Hospital. And last year I said you know what, we got something, I'm going to reach out to this doctor, **[identifying information redacted]**, who's been doing scientific study down there, and give him this uniform just so he can test it and see what's going on, with a lot of people who has been diagnosed with this.

This was a vehicle, this is a vehicle on how and what people were facing. Can I pass it around? This is not a do-right or do-wrong situation to the first responders; this is a life-or-death situation for the first responders. That's why you see so many of -- that's why you see so many of the police and firemen and all the other city workers and first responders coming down here to support this situation.

I'm not going to take up a lot of time. It's very emotional. I have been also diagnosed with asthma today but it could be cancer tomorrow. I just implore you that could have been your husband or your wife, your son or your daughter, your child, your family member. This is a real surreal situation. This is why I want you to bring -- I brought in the uniforms. Just imagine you being down there, you on the panel being down there, succumbing to all this smoke, this dust, covered in this. And now ten years later, we here to fight for putting one thing on the bill. The right thing to do is to add cancer into the bill. Thank you so much.

DR. MIDDENDORF: Thank you very much, Mr. Harris. Mr. Harris? Is it possible to get a copy of this photograph that you're sharing with the committee?

ALONZO HARRIS: Yes, it is. Sure.

DR. MIDDENDORF: If you could send it to me by email or whatever, I would appreciate it.

ALONZO HARRIS: All right.

DR. MIDDENDORF: The reason I need it is that we need to be able to put it into the docket.

ALONZO HARRIS: Can I walk around with the uniform so they can just see -- for you guys to see, if who wants to see it, they can see it --

DR. MIDDENDORF: Sure. Sure, go ahead.

ALONZO HARRIS: -- on a close-up basis.

(pause)

DR. MIDDENDORF: Thank you very much, Mr. Harris.

Our next presenter is on the phone. Ken Zevekus (ph). Mr. Zevekus, are you on the phone? If you are, please unmute it.

KEN ZEVEKUS: Yes, can you hear me?
DR. MIDDENDORF: Yes, we can hear you now.
KEN ZEVEKUS: Okay. Good morning. Thanks for giving me the opportunity to speak to you, today. I'm a retired New York City chief officer. I was there on 9/11, and I would like to share something with you. I don't know how old the panel is but I'd like to give you some new information that you may not be aware of.
Ironically in 11 more days it will be the 37th year anniversary of the infamous telephone company fire in New York. Over 440 of my brothers responded to that fire that day, and within five days of that fire, roughly 200 of them had chest pains, couldn't breathe, all other types of respiratory maladies. And approximately ten to 15 years after that, half of that number, roughly 100 of those guys, were dead from cancer.
Now in the ensuing years, through the federal government and various OSHA and NIOSH programs, it was determined that there was -- this was our first exposure to a hazardous material, polyvinyl chloride, and in the early 90s, some other unique information was discovered that the New York City Fire Department had the highest cancer rate in the nation -- in the world, because we responded to the most amounts of incidents and fires that any city that would ever have.
I was part of a small group; I was part of 14 unique individuals who were given over 225 hours of training, brought up to what they called the technician level; and it was our job to transmit to first responders: police, fire, all first responders, military, that the exposures that we were likely to have at chemical fires, hazardous material fires, things like that, never thinking that ten years later, roughly 2001, it would be deja vu; it would be all over.
You talk about going numb? The second that plane hit I knew what was going to happen because I knew every single one of us who were going to be there, all the firemen, all the cops, all the innocent bystanders who got caught up in that whirlwind, that we were going to become a new panel of statistics, and sure enough, just like at that World Trade Center -- I'm sorry, the telephone company fire, approximately ten years after that fire, all of a sudden this stuff starts to manifest itself again.
I don't know why it's taking a brain surgeon or a nuclear physicist to even think about that that cancer didn't come because of what we all were exposed to on that date. I think it's criminal; I think it's immoral for anybody not to admit that, that that's a possibility.
We didn't go there because we were getting paid. We were professionals, we were highly motivated, we were motivated to save human life, something that only God, I was brought up, could do. But we were trying to be like God that day and we

were trying to save as many of our fellow citizens as we could.

And a lot of us now are starting to pay the price for that. I'm asking that you, I'm asking that governments, municipalities, whoever, step up and do the right thing now for us, like we did the right thing for you on that day. Thank you.

DR. MIDDENDORF: Thank you very much, Mr. Zevekus. Our next commenter is also on the telephone, Victoria Gilles (ph). Ms. Gilles, if you're there, please unmute.

VICTORIA GILLES: Yes, good morning.

DR. MIDDENDORF: Morning.

VICTORIA GILLES: I'm a good will ambassador from Washington State, and after 9/11 I did, with the Seattle Benevolence Association, I did a big event raising $50,000 for the widows' and children's fund for the FDNY. Deputy Chief Nick Visconti, at the time, attended that, along with Assistant to Chief of Department, **[identifying information redacted]**, who died on 9/11, **[identifying information redacted]**, attended this event.

After we had raised the money I took the check back to New York City. I visited a lot of stations, seeing a lot of the memorials, listening to a lot of stories from a lot of the men and women that were telling me about their brothers and sisters that were lost. A lot of the men would say to me, would -- they're not going to remember us. They're going to forget. And I would say to them, who could ever forget this? Who could ever forget this tragedy? But they believed that they would be forgotten. In April of last year when bin Laden was caught, on the day he was caught, my friend, **[identifying information redacted]**, when I talked to him on the phone, had told me he was diagnosed with esophageal cancer. His comments to me were: I'm a Vietnam vet, 9/11 vet, I watched my best friend die on 9/11, and I took care of his kids from there on out, they lived across the street from me. This is what it comes to for me at 58 years old, this is what it comes to my brothers and sisters that are dying in record numbers.

I made a promise to him, that his government did care. And he kept saying they don't care. They don't care about us. I said I will help you with whatever I can. He sent me a newspaper article that was telling me about the James Zadroga Bill. He asked for my help. He said, I will be dead in two months, Vicky. But whatever you can do to help me and to help my brothers and sisters that this is going to happen to, because rest assured it's going to happen, would you please do it? I said absolutely, I will do what I can.

I am married to a first responder, to an incident commander, who, as he watched the World Trade Centers come down, as we all did on that horrific day, kept saying to me, where's the respirators? Where are the respirators? Why do they not have

respirators on? There were very few people wearing those respirators in that toxic dust. Of those towers that were built in the 1960s, that it was obvious that with asbestos and everything else that was going on, there was going to be problems later.

The U.S. needs to take care of their own. I wrote letters to 14 senators and congressmen. Senator Steve Hobbs, from Washington State, is the only one that spoke up. He sent letters to U.S. Congressman Adam Smith, who spoke up and has been letting me know what they're -- what they've been doing since then.

It is shameful as people from the United States that we are not taking care of our own, our own heroes, when we take care of everybody else out there. It is shameful it's been ten years. It is shameful that politicians went to bat for the James Zadroga Bill, which had to do with cancer, and then took cancer out of the bill.

First responders are not meant to go to war. They are meant to save lives in fires and accidents and things like that, but not war. We owe it to them as our heroes to do the right thing. Do we actually expect, as a police officer before me said, for them to go back into anything that might happen, and with terrorist attacks happening right now around the world, this could happen again in the State of Washington. Does it need to happen in our own back yard before we get the big picture? Do we actually expect them to go back into buildings such as the World Trade Center, the Pentagon, whatever, and do the same thing over again, when we are not taking care of them?

I want to say to the people on the phone, I understand what you're going through. My husband and I care. We care. There are people that care. And we will fight this until something is done. We are not going away. Thank you.

DR. MIDDENDORF: Thank you very much, Ms. Gilles. Our next commenter is Stephen Levin. Okay, I don't see him here. You don't happen to be on the phone, do you, Mr. Levin? Okay. Again, I'll move him to the back of the list and then we'll call on him to see if he happens to show up.

So we'll go to the telephone again. Eric Ashlie. Mr. Ashlie, are you on the line?

ERIC ASHLIE: Yes.

DR. MIDDENDORF: Okay.

ERIC ASHLIE: Can you hear me?

DR. MIDDENDORF: Yes, we can hear you.

ERIC ASHLIE: All right, thank you. My name is Eric Ashlie, and I'm calling today on behalf of Washington State Senator Steve Hobbs. First I wanted to thank the committee for allowing testimony on this matter. It's extremely important and I appreciate that. More importantly, thank you so much to those of you that have

testified before me yesterday and today.

Those who were at Ground Zero on the front lines over ten years ago deserve more than what Congress has offered them in the current legislation. The first responders of 9/11 are America's most courageous men and women. Victoria Gilles, who just spoke, came to us back in August and said, she basically said exactly what she just said to us, and we were astounded that cancer had been taken out. While I understand that the first review that came out did not establish presumption of cancer, since then we have seen a series of studies that do so. Now is the time for the committee to recognize this opportunity and recognize the men and women who were brave enough to step up for their country -- for our country, back on September 11th. I know there are a lot of people that want to testify today so I'm going to keep it short, and we've already provided written testimony. God bless all of those of you that have been part of this experience and have family and friends that have been affected. Thank you so much. That's all I have.

DR. MIDDENDORF: Okay. Thank you very much, Mr. Ashlie.

Our next commenter is Esther Regelson.

ESTHER REGELSON: Hi. My name is Esther Regelson, and I live three blocks south of the World Trade Center site. I was caught in the dust cloud on September 11th and moved back into my apartment five months later.

The EPA conducted no testing or cleanup of our building, although it said it was contaminated. To this day I am uncertain to what degree my apartment and the rest of my building were cleaned of the World Trade Center dust, raising concerns about further exposures long after the events of 9/11.

Although I had preexisting asthma, my asthma worsened significantly after 9/11. Subsequent tests at the World Trade Center Environmental Health Center showed that my lung capacity was only 43 percent of normal. Thankfully that capacity has increased due to the specialized treatment that I have received at the WTC EHC.

I'm a member of the World Trade Center Health Program survivor steering committee. And on behalf of the committee, I would like to summarize our ideas regarding NIOSH's WTC research approach and priorities. The survivor steering committee plays an advisory role in the administration of the survivor health program, and represents the community of affected non-responder WTC stakeholders.

First, there are a wide range of knowledge gaps with respect to science, biology and treatment of WTC-related illnesses. NIOSH should close these gaps by supporting a diverse portfolio of studies at different levels of funding that includes pilot studies, clinical trials, studies of disease mechanisms, epidemiological studies and basic science research. We urge the creation of key resources that are useful to multiple

investigators.

Second, NIOSH should encourage and fund proposals that address health effects to survivors as well as responders. Studies of survivor populations should address health effects on those living, working and attending school in the impact zone defined by the Zadroga Act and represent the diverse populations and geographic areas affected. Wherever feasible, cancer incident studies must include survivors as well as responders.

Third, NIOSH should recognize that WTC research is disaster science. Especially with respect to the survivor community, researchers are operating in the absence of preexisting baseline data or comprehensive environmental measurements from which to assess exposures. These limitations must not become an insurmountable barrier to meeting the health needs of 9/11 survivors.

Fourth, NIOSH should encourage researchers committed to collaborating with affected communities, using a community-based participatory research or CBPR model for their studies. The benefits of the CP -- BPR model are well established.

Fifth, NIOSH must strengthen the surveillance function of the data centers to gather and analyze data in a timely fashion. Otherwise there is little chance that important trends, including the emergence of new conditions, will be recognized.

Sixth, NIOSH should ensure that all research proposals receive proper peer review by including appropriate specialists. We also have the following recommendations regarding WTC Health Program research priorities for the survivor population: one, given children's increased susceptibility to harm, especially in critical periods of development, it is imperative that NIOSH move quickly to support in-depth studies of respiratory, developmental and endocrine health impacts for this rapidly dispersing cohort; two, we recommend that blood samples be collected from WTC-exposed children and preserved for later analysis including the freezing of live cells containing genetic markers. These samples could prove useful in at least three ways: as potential source of biomarkers for exposure to WTC toxics, as a source of protein markers of disease with potential use in diagnosing and understanding WTC-related illness, and as a source of genetic material which can be analyzed for evidence of genetic alterations relevant to disease that may be detected many years after exposure.

Strong protocols to protect privacy of all data must be developed in consultation with the survivor steering committee.

Three, because so little is known with respect to inflammation and other underlying mechanisms for WTC illness such as sarcoidosis, cancer and asthma, it is critical that NIOSH support studies of disease mechanisms.

DR. MIDDENDORF: One minute, please.

ESTHER REGELSON: I'm almost done. Four, cancer incidence and prevalence must be tracked across all WTC populations.

And five, last, in addition to -- in an analysis of WTC EHC patients, 60 percent screen positive for mental health condition, 40 percent of whom had symptoms of PTSD, anxiety and/or depression. Those with lower respiratory problems seem particularly vulnerable.

There is a growing literature on the impact of parental PTSD and depression on children's mood, anxiety and behavior, including one study among 9/11 survivors. It would therefore be valuable to investigate the impact of parental mental health disorders on their children's mental health as well as children's mental health on their parents. This would provide essential information about the intergenerational transmission of mental illness after a terrorist attack. A version of these comments has been submitted by our committee co-chairs to the NIOSH docket. On behalf of the committee, thank you for your time.

DR. MIDDENDORF: Thank you very much. Next commenter is Fred Krines.

FRED KRINES: Good morning. My name is Fred Krines; I'm employed by the New York City Police Department. On September 11, 2001, as the disaster occurred at the World Trade Center, I was one of the first responders, thereafter as a volunteer. Me and my coworkers responded over there without hesitation. We dug through the piles and thereafter that I also was ordered to go over there. 2010 of June, I was diagnosed with follicular dendritic cell sarcoma, a very rare cancer. (Indiscernible)-wise, there's 50 of them in this world today. I had a radical (inaudible)-section performed June 2010 with (indiscernible) treatment after that, chemotherapy and 45 days of radiation. I'm asking you to add cancers in the bill for medical treatment.

I was very lucky that the doctors caught this on time, and they performed surgery. 'Cause if it wasn't, I would have been dead today. And that's all I want to say.

UNIDENTIFIED SPEAKER: I couldn't hear what kind of cancer it was.

FRED KRINES: Follicular dendritic cell sarcoma.

UNIDENTIFIED SPEAKER: I don't know what that is.

FRED KRINES: It's a very rare cancer; there's maybe 50 of it known worldwide. I have documentation over here for it, if you want to see it. And it's just, like the doctor said, it's just I have to go for PET scans every six months because it's a rare cancer that nobody knows about. I just want to have the doctors of the panel over here just to recommend cancers in -- when they go in front of Congress next month so people could have a chance to live. Thank you.

DR. MIDDENDORF: Thank you very much. Micki Siegel de Hernandez.

MICKI SIEGEL DE HERNANDEZ: Good morning. My name is Micki Siegel de

Hernandez, I'm the health and safety director for the Communications Workers of America; we represent mostly nontraditional responders as well as area workers.

I wanted to make a few comments about the Sinai study results that were reported on yesterday by Dr. Landrigan, particularly for those of you on the panel who are still wedded to the idea that epidemiological studies are the ultimate proof needed to add cancer as a covered condition.

I wanted to comment on the ways in which these studies, lake the Sinai study, are an underestimate and an undercount of the true rates of cancers.

When I consider these limitations, it makes the Sinai analysis and their results even more striking. For one, the results are for a portion of responders, not the entire group of responders, the true number of which is actually unknown. As you heard testimony today, none of the national -- the thousands of national responders are included in any of these studies. And this is especially important with regard to rarer cancers, but certainly for all.

The results are also based upon patient matches with cancer registries, the Sinai results. The New York State Cancer Registry has a two-year lag time. The New York State Cancer Registry -- in other words, the more recent, these past two years, cancer cases reported to the New York State Cancer Registry, would not be counted in the Sinai results.

The New York State Cancer Registry is also better at capturing certain cancers, solid tumors, less so for others. Blood cancers, one of the World Trade Center cancers of concern, most concern, are less likely to be reported and counted in the New York State Cancer Registry.

Fourth, as other commenters have talked about today, many responders with cancer are not part of the World Trade Center Health Program for many, many reasons. When I speak to our union members with cancer, and there are many, some of which with multiple cancers in addition to their other World Trade Center-related disease, I always ask if they are a patient in the World Trade Center Health Program and if not, why. These are the two most common reasons for nonparticipation: first, obviously when a person has cancer, their life is consumed by their disease and their treatments. The World Trade Center Health Program does not currently cover cancer and so many people see no reason to be part of the program. And to go for more doctor visits on top of what they are already dealing with in their lives.

The second reason for nonparticipation for many people is that they are just plain angry, and understandably so, that their diseases have not yet been recognized and covered in the program, and they refuse to participate for that reason alone.

Finally, I would like to comment about the selection of certain cancers, and I worry

about cherry-picking which cancers to include given the incredible range of carcinogens and other contaminants that people were exposed to. This would be a huge disservice to those people who were simply unlucky enough to get the wrong cancer at this time, like the gentleman who just testified. It also worries me because it is hard to imagine a way in which additional cancers, one by one, especially rarer cancers, will ever get added to this list unless record number of responders and others contract a particular disease, get sick and die.

As Dr. Melius said earlier, your decision is ultimately about enabling those affected to receive care to get that care. I personally would rather fight for adequate funding for both the World Trade Center Health Program and the victims' compensation fund than exclude those deserving of this care. I hope you keep all these things in mind today as you deliberate. Thank you.

DR. MIDDENDORF: Thank you very much. Bill DeBlaiso? Apparently he was held up downstairs. We'll move him to the back of the line again. Jo Polett?

JO POLETT: My name is Jo Polett, and I live at 105 Duane (microphone issues). How's this? Okay. My name is Jo Polett, and I live at 105 Duane Street, a 52-story high-rise located seven blocks north of the World Trade Center site. Constructed in 1990, the building has no asbestos-containing material.

Yesterday we heard panelists and members of the public note the disconnect between reassuring government sampling results and the health effects of many of those exposed to World Trade Center dust and smoke. The 2002 ATSDR NYC DOH final technical report of the public health investigation to assess potential exposures in settled surface dust in residential areas of lower Manhattan. A good example of that disconnect is cited on page one of the NIOSH February 2012 WTC OPC document prepared for this committee.

I'm concerned that someone hoping to learn something about residential exposures might read the ATSDR NYC DOH study, so I'll spend a few minutes telling you what I know about it.

In November and December of 2001, ATSDR NYC DOH sampled in and around 30 residential buildings for asbestos, SVF and mineral components of concrete and building wallboard.

You may recall that at the last meeting of this committee I provided you with asbestos and lead sampling results from my building. I'll quickly reprise some of the asbestos results. On December 3rd, 2001, CIH sampled the supply air diffuser on the tenth floor, sample was collected by MicroVac and analyzed by TM for asbestos. The sample tested positive for asbestos at a level of 550,000 structures per square centimeter; that's 50 to 500 times above expected background.

Additional subsequent sampling of the entry door frame of a fifth-floor apartment

yielded a result of 123 asbestos structures per square centimeter, indicating that the ventilation system was circulating asbestos through hallways and into apartments, sampling of the fan coil unit of the living room heating and air conditioning in that unit yielded a result of 37,000 asbestos structures per square centimeter. Not only was my building one of the 30 buildings sampled by ATSDR NYC DOH for their study, but the fifth floor apartment, the results I just cited, was one of the two residences in the building that was sampled.

Yet according to the ATSDR NYC DOH report, no asbestos was found in the common areas of the building or in either of the apartments that were sampled. How is that possible?

According to the comments of **[identifying information redacted]**, an asbestos expert who reviewed the study when he served on the peer review committee for EPA's exposure in human health evaluation paper in 2003, quote, I think that asbestos was likely present in all of the bulk samples collected and that the failure to detect asbestos in many of the indoor settled dust samples or the outdoor samples was a question of deficiencies in either the analytical method or the conduct of the method.

So what was the purpose of conducting such sloppy sampling? Well, we were informed of these results in January of 2002, during a dispute with the landlord about whether and how to clean the ventilation system.

DR. MIDDENDORF: One minute, please.

JO POLETT: A letter from New York City Department of Health, stating that there was no asbestos at 105 Duane Street was distributed to every tenant in the building along with a 105 Duane Street fact sheet compiled by the New York City Department of Health, disputing the validity of our finding and condoning the landlord's plan to use a company that was not certified in asbestos and had never cleaned a tall building to clean the ventilation system. I mean, this looks pretty innocuous. Here's the study but this study, like the EPA sampling results, were weaponized and used against us when we tried to make our building safe for habitation. Thank you.

DR. MIDDENDORF: Thank you very much. The next presenter is Jewell Bachrach.

JEWELL BACHRACH: Good morning. I'm Jewell Bachrach. Can you here me? I live at 18 North Moore Street, which is the northern end of the accepted community that has -- is supposed to get response by government forces. I've lived the majority of my years down here -- lived and worked. I've lived here since 1968 of -- when the -- however, when the report came in after analyzing my apartment, it had asbestos, and now to -- and two years ago I was operated on for lung cancer, although I have lived a very healthy lifestyle. I never smoked in my life.

One of the problems is no one's ever cleaned, even though it's supposed to be the area which all this debris has fallen and which you know to be really serious problem -- no one's ever cleaned the outside of the buildings. I don't know what's happened in 2012. I bet you could find something now. I mean, even though I live a half a mile away, they found, they found asbestos and I mean, it shocked me that I have -- that I had lung cancer. It was luckily caught comparatively early. But I'm constantly bombarded with radiation because they need to take tests every few months to find out if I'm still clean. You know, I'd like some other way to die. I'm going to be 80 and I want to live a little longer.

I really think cancers should be considered one of the problems here, since that should not have been a reason for me to die. I mean, I haven't lived a life like that. Please, please do consider it. You've had very excellent people who have come up here, who have really analyzed the situation and where -- it's -- where -- further work could be done. That's fine. But no one in this operation knows that I had cancer. It was just lucky -- I mean, I was just lucky in that since I was more than 65, God bless Medicare, had paid for it.

One week in the hospital cost the federal government for me $92,000, and yet the only medication that I got, that I asked for was a vitamin pill and a stool softener plus a little numbing of my nerve endings after the operation. That's all I got. And the bill was $92,000. You know, come on, help. Thank you.

DR. MIDDENDORF: Thank you very much, Ms. Bachrach. Our next commenter is Bill DeBlaiso. Apparently he's downstairs in line and trying to come up. How about Collin Ecosta? Or Stephen Levin? Mr. DeBlaiso?

BILL DEBLAISO: Thank you very much. Thank you for the opportunity to speak before you today. I'm sorry I'm running a few minutes late, I'll be brief. Good morning to everyone and I'd like to thank the committee for addressing the critical issue of adding cancer to the list of World Trade Center-related health conditions as specified in the Zadroga Act.

As public advocate for the City of New York, I am reminded regularly of the horrors of September 11th, 2001, and the tragedy brought upon our city. Unfortunately many of our men and women who served as first responders on 9/11 and in its aftermath remember that day for a far different reason. They are currently suffering from cancer as a result of the toxins that were exposed to -- that they were exposed to during the recovery and cleanup operations.

Mt. Sinai Medical Center has treated thousands of first responders and it's conducted extensive research into the connection between illnesses these individuals have developed and their exposure to toxins at Ground Zero. I recently called on the City to provide Mt. Sinai with all available information regarding New

York City police officers who served at Ground Zero and subsequently developed cancer. But while the City obfuscates, these individuals suffer, and even more fear the day when they may be diagnosed further.

When the planes struck our city on 9/11, these brave men and women answered the call of duty, never once pausing to think about long-term health implications. In the days and weeks following 9/11 many of these first responders continued to work around Ground Zero and at the Fresh Kills Landfill, breathing in the toxins that cause their suffering today. They worked in difficult conditions surrounded by a cloud of dust that contained known carcinogens such as asbestos, benzene and dioxin. Any of these elements on their own would be extremely dangerous; mixed together in the air, they have proven deadly.

Research by the New York City Fire Department has found a 19-percent higher cancer rate among FDNY members who had been at Ground Zero than among those who had not. Mt. Sinai has already found four cases of multiple myeloma among responders under age 45, an extremely young age for diagnosis. Just recently cancer-causing toxins were found on the uniform of **[identifying information redacted]**, who survived being buried in the World Trade Center debris on 9/11.

I understand the purpose of this committee is to review scientific and technical information in order to make a recommendation to the administrator of the World Trade Center Health Program, yet common sense shows us the suffering is real. These individuals are struggling and dying of cancer right now.

The Patrolmen's Benevolence Association has found at least 297 officers who served in the World Trade Center operations have been stricken with cancer. Another 66 have died of cancer since 9/11. Before September 11th, 2001, an average of six police officers per year were diagnosed with cancer, so again, 297 officers have been stricken since 9/11, 66 have died. Previous to that an average of six police officers a year were diagnosed with cancer. Ever since the attacks an average of 16 police officers a year are now diagnosed with cancer, constituting an increase of nearly 300 percent.

The NYPD lost 23 officers on September 11th, 2001, but even more have given their lives since that tragic day as a result of cancer they developed in the aftermath of the attacks. Take the story of **[identifying information redacted]**. Officer **[identifying information redacted]**, a native of Mount Vernon, spent over 200 hours down at Ground Zero, working 12-hour shifts, breathing in toxic air that we know was filled with carcinogens. In 2007, while in his early 40s, **[identifying information redacted]** was diagnosed with a stage IV flat skin tumor, which is a cancer of the bile duct.

DR. MIDDENDORF: One minute, please.

BILL DEBLAISO: This is an extremely rare form of cancer that usually develops in

patients older than 65. Officer **[identifying information redacted]** had no history of cancer in his family. The only known risk factor he had for developing this rare type of cancer was exposure to toxins, including asbestos and dioxin, which were present in the air, dust and debris at Ground Zero.

As Officer **[identifying information redacted]** fought for his life, he also advocated for the passage of the Zadroga Act with specific inclusion of certain types of cancer on the list of World Trade Center-related health conditions. Sadly, he lost both fights. But here today you can right -- at least right one of these wrongs by recommending that cancer be added to the list of World Trade Center-related health conditions so that every first responder suffering from these rare cancers, can get the help and support that Officer **[identifying information redacted]** never had the chance to receive. Please don't let his story get lost in your analysis because the City refuses to turn over all of the necessary data for this study.

That our first responders are suffering without needed medical care is outrageous and shameful. As their advocate, I strongly urge you to include cancer under the James Zadroga Health and Compensation Act. Thank you very much.

DR. MIDDENDORF: Thank you very much. Mr. Levin?

STEPHEN LEVIN: Thank you very much, members of the committee, for the opportunity to testify before you this morning. In the interest of allowing frankly more important testimony this morning from first responders and professionals, I am going to keep my remarks very brief.

My name is Stephen Levin, I am a council member for the 33rd district in Brooklyn, and I am here today to strongly urge you to include at the very least some cancers, including but not limited to blood cancers, including leukemia, lymphoma and myeloma, nasal cancers, thyroid cancer and prostate cancer. And for those currently that -- and those cancers that currently meet less of an evidentiary standard, that this committee continue to study them very closely.

From the testimony that you have heard over the past day, the anecdotal evidence is absolutely overwhelming and in my opinion indisputable, that certain cancers are linked to work at Ground Zero. However, I believe that this committee is beginning to see clear scientific evidence emerge that even more firmly establishes that link.

I serve on the Lower Manhattan Redevelopment Committee on the City Council. Two and a half weeks ago, we held a hearing on the 2011 report of the New York City World Trade Center Medical Working Group. Frankly I found this report and the Bloomberg administration's answers to my questions to be very frustrating. The report says, quote, the first World Trade Center cancer risk study to be published found that firefighters with World Trade Center exposures may be at a greater risk for cancer than firefighters who weren't exposed. I call that the

understatement of the year considering that the FDNY report found a 19- to 30-percent increase in cancer among firefighters who served at Ground Zero.

In response to my questions about how many studies would be needed to establish a scientific link strong enough for this committee to proceed with covering cancer, **[identifying information redacted]**, Deputy Commissioner of Epidemiology at New York City Department of Health, demurred.

While yesterday this committee heard some preliminary results from **[identifying information redacted]** of Mt. Sinai on their study -- on their World Trade Center Health -- their study of the World Trade Center Health Program, showing a 14-percent increase among a broad range of cancers. The question I ask is when is enough evidence enough?

I found his challenge to this committee to be particularly appropriate. And I won't try to paraphrase but I will put my own spin on it.

Knowing that you will never in many years achieve a 100-percent ironclad proof from epidemiological perspective of a Ground Zero to cancer link, when does this committee make the judgment based on overwhelming anecdotal evidence, a growing number of medical studies, and just plain old common sense, to vote to have certain types of cancers covered under the Zadroga Act, in accordance, I believe, with the intent and spirit of the legislation? I believe that that time is now and that this committee should listen not only to all of the growing evidence but also to its collective conscience. If you do not act, for far too many, justice delayed will be justice denied. Thank you very much for the opportunity to testify.

DR. MIDDENDORF: Thank you very much. One last call for **[identifying information redacted]** ? Apparently **[identifying information redacted]**has decided not to provide his comments.

On behalf of the committee, let me thank each and every one of the public commenters of today and yesterday, both here in person and on the phone, and also those who have submitted their written comments. It really does provide the committee with a very different perspective than they can get from just reading the literature and I think it's, I think, very beneficial for them, so we very much appreciate you taking the time and effort to come and present your perspectives to them.

DR. WARD: Thank you. So at this point we'll take a 15-minute recess and be back promptly. We'll be back promptly at 10:40. Thank you.

(Recess taken 10:25 a.m. until 10:53 a.m.)

DISCUSSION OF PETITION ON CANCER

DISCUSSION OF PETITION ON CANCER

DR. WARD: So Paul is going to call the roll and then we are going to --

DR. MIDDENDORF: I'll just make a note of it.
DR. WARD: Or just make a note of it; and then Paul wants to say a few words about our overall charge and perspective.
DR. MIDDENDORF: Okay, I think as we begin to really think about the issue before us as to whether or not to add canc -- or make any recommendations or provide advice to add cancer or a specific type of cancer, make that recommendation to the program administrator, we need to know a little bit about what the needs of the administrator are.
It's important to recognize that whatever decision the committee makes and whatever recommendation it makes to the administrator, the administrator needs -- will then take that information and make a decision whether to move forward with the recommendation or how to move forward with that recommendation, anywhere from fully accepting it, going beyond it, not accepting it, whatever. What would be most helpful to him in help -- in making that decision is if the committee spends a lot of time really critically analyzing the underlying assumptions, the underlying science that they are making that decision -- or what they're basing that decision on.
So I think in this particular case, since we have a very unique situation where we all recognize that the available science is rather limited, there are large gaps in our knowledge, in fact the information is evolving rapidly as we're trying to make the -- this decision. So it's very important that all of the assumptions, all of the information, be critically looked at so that there is a robust record that the administrator can use to help make him -- to help him make a decision on where he wants to go with the recommendation.
I think the other thing that we need to recognize is that there's sort of a 600-pound gorilla in the room, and that's that each of the members, I believe, has a deep respect for each and every one of the responders and survivors who's been impacted by the attacks on 9/11. But, while each of us has that respect and we want to honor those people, we need to make sure that that does not prevent us or inhibit us from really looking at the science, understanding what it says, what is doesn't say and what additional information might be needed, what the assumptions are. So, while we want to honor those responders and survivors, we want to make sure that they understand that they are respected by the committee, the committee needs to feel comfortable having that open discussion, having a robust discussion, so that in the end the program administrator can make a good decision on what to do. And in the end it is somewhat paradoxical if the committee does not provide a good robust discussion, then what may happen is that things may not go forward appropriately, it leaves the administrator open for

attack or whatever -- not attack, for questioning. So that if he tries to move forward with a rule to add cancer or a specific type of cancer, what could happen is that it would be questioned more thoroughly. So paradoxically it may wind up actually hurting or inhibiting the ability of the administrator to provide the relief that the committee feels is appropriate if they don't do a good job of describing the science and the underlying assumptions.

DR. WARD: And I think you all heard -- or the committee at least heard yesterday, I did have the idea of taking a poll. That's one way to start off the committee's deliberations. I think in terms of where we are at the meeting, that's probably not a good way to go. I think the way the poll is constructed really doesn't capture the complexity of peoples' opinions, so what I'd like to do as an alternative, though, is to give everyone on the committee the opportunity to speak about where, you know, where they stand on the issue at this point of whether cancer in general should be listed as a World Trade Center-related condition or whether specific cancers should be listed.

What Paul and I will do, and I'm hoping Paul will do this, is I am eager to really record this in a systematic way. So even though people don't have to express a specific opinion about specific cancer sites, if they do express that opinion, we're going to try to tabulate it so at least we know where the committee stands in relation to specific sites.

I probably will take some notes, and what I'm going to be taking notes on is more some of the larger issues, such that when we do write up any recommendations to Dr. Howard, I can make sure that, and we will have the transcripts, and we will have the notes, but I'm not sure we'll have all of those things in the time frame that we need to write the letter, so I am going to take some notes just to make sure I capture some of the important ideas. So if that's agreeable to everyone, I'd like to start. And I don't, I -- Steve, did you?

DR. MARKOWITZ: I have a question. I have a question. The question is: I don't know if this is on or not but --

Does Dr. Howard want advice on specific cancers above and beyond a recommendation about cancer in general?

DR. WARD: I think the way he phrased his letter is yes but I'm sure Paul or someone else from the NIOSH staff... I think it said something like cancer or specific cancers but we'll verify that.

DR. MIDDENDORF: Yeah, it's right here.

DR. WARD: Yeah. It's phrased as, on whether to add cancer or a certain type of cancer to the list.

DR. MARKOWITZ: So if I could suggest a way of talking about it, perhaps we could

have an initial discussion on, in general, whether at least some cancers are related to exposures, and then secondarily talk about specific cancers, as opposed to mixing the two topics into the same conversation.

DR. WARD: So you're saying, just to make sure I understood you, first ask peoples' opinions about whether specific cancers should be listed and second, to talk about the issue of cancers overall? Is that what you're --

DR. MARKOWITZ: Well, in reverse order.

DR. WARD: Oh.

DR. MARKOWITZ: Yes, the different -- have a first, a broader discussion about whether any cancers are related and then secondarily what specific cancers, specific cancers we would recommend.

DR. WARD: Okay. So that's a little different from what I said but I think I understand it now. Okay, whether any cancers and then, and then if yes, which cancers. And Glenn?

DR. TALASKA: My question was about the process that we're going to go through with this. Are we planning, if we do make a recommendation one way or the other, that we will have subcommittees to draft the response, or what's your idea as far as how we're going to proceed if we do, regardless of what the outcome is? Paul's got an answer.

DR. MIDDENDORF: Yeah.

DR. WARD: Good.

DR. MIDDENDORF: Whatever you decide has to be done in an open meeting of the full committee. So either it needs to be drafted today while we're here or we need to try and establish another, a meeting. Those are part of the FACA rules. It's a federal advisory committee; it has to be done in an open meeting.

DR. WARD: So one option again, depending on how difficult the task is going to be and how much, I mean, this is not going to necessarily be a 50- page report; it could be a two- or three-page report so, so one option, I think, that might make sense is that I could draft something and then we could have a teleconference to discuss the draft and make any changes that we want to make.

DR. TALASKA: My only concern is with the documentation. If we're going to document this well, it's going to take some time to document and can't be done just ad hoc, at least from my point of view; I'm not that bright. So I can't provide all the references that one would consider including to make sure that the documentation is robust.

DR. WARD: Okay, well, why don't we wait until the end -- towards the end of the meeting to address that, when we have a better sense of what we're talking about?

DR. TALASKA: Okay.
DR. WARD: But I understand your concern and we'll figure out some way to incorporate everyone's input.
Was there anyone else who wants... Yes.
MS. DABAS: I just want to know if the recommendation had to be unanimous amongst the committee or just majority, and whether there was going to be your opinions written?
DR. MIDDENDORF: Whatever the recommendation is, it needs to be a majority of the committee, a majority of the voting members, according to our bylaws.
DR. WARD: Okay, so I think the question we'd like to address first, and I'll ask for volunteers, you know, to speak, but I would love to hear from as many members of the committee as possible so we really have a sense. And so the question we're going to address first is whether we think any cancers should be listed as World Trade Center-related.
And I'd like to give the people on the phone the opportunity to speak first, not to put them on the spot but just to make sure they have the opportunity. If you would prefer to defer until later in the discussion, that's okay, too, but let me know if you'd like to speak.
DR. DEMENT: This is John.
DR. WARD: John, John, sorry.
DR. DEMENT: I guess, I feel like we're sort of going a bit backwards with regard to any cancers, and if you're asking me for a comment with regard to I think it's reasonably anticipated that cancers will result -- will come about as a result of this exposure, my answer would be yes. But then I have some concerns about a general statement about cancers.
DR. WARD: So let me just paraphrase to make sure we understand. So you're saying you think it might be reasonable to say that some forms of cancer might reasonably be anticipated to occur but maybe not reasonable to say all cancers? Is that...
DR. DEMENT: Well, I, I think it's reasonably -- it's a reasonable anticipation that cancers will result from this exposure; however, I think we need to then go from there with some more discussions about types of cancers that have greater support for that conclusion.
DR. WARD: Okay. One thing we've done in the room is we put up kind of a standardized list of cancer types. We've put up a standardized list of cancer types and I don't know if there's a way to -- which is from the American Cancer Society's Cancer Facts and Figures, but it's the same kind of classification that's used by pretty much everyone for human cancers. So Paul, if you can get it to show the

full screen, that would be great. And this is just so that when we refer to -- if we want to refer to cancers of different organ groups.

DR. MIDDENDORF: That is full screen.

DR. WARD: This is just a tool to help us communicate. It's nothing more than that. And people can access this online if they're at home at an internet by going to the cancer.org website and looking for the facts and figures publications.

Okay, so Virginia, any comments now or do you want to hold off until later in the discussion?

DR. WEAVER: No, I do want to comment now because I will not be able to rejoin you after lunch, so... I would concur with John that I think that World Trade Center exposures will increase risk for cancer.

I think there may well be specificity within particular types of cancer, and I base that based on tox knowledge and work with firefighters exposed to combustion products.

I also think that in documenting our determination, there are some things that are critically important to include in that because no matter what decision we make, it will be -- it will generate a great deal of discussion, and so I think it's very important to document the discussion we had yesterday about measurable increased risk in cancer from only a month of asbestos exposure, about decreased breast cancer rate with cessation of HRT, and I also think Liz made some comments about radiation that -- I was trying to teach and couldn't hear all that well, but I think that it's very important that we document measurable increased risk from short-term or relatively short-term exposures.

And then I think that it's important that we, if we go forward with some type of cancer recommendation, clearly document that we are not sitting and waiting for epidemiology, that there are other lines of science that we can use to move forward.

DR. WARD: Thank you.

So now turning to other members of the committee, maybe you can signify with your tent cards when you'd like to speak. Steve has his tent card up.

DR. MARKOWITZ: I also think that at a minimum there's a reasonably strong likelihood that at least some cancers will have or will result from World Trade Center exposures. A reasonably strong likelihood that cancer has or will result from World Trade Center exposures, and I have a number of components of an argument that, if I can go through some of those:

One is the, the fact that many established human and suspected human carcinogens were documented to be present in the dust, or in the dust or smoke, at that time.

Secondly, we know that there were certainly ample exposure to World Trade Center dust and smoke, not so much documented through many of the sampling but documented through both knowledge about what occurred at the site, but also I'm impressed by the magnitude of the nonmalignant disease that's occurred among World Trade Center responders.

Third, we heard some information about the relationship between relatively short exposures and cancer. Not saying that all exposures there were short because we know that community exposure probably continued over a number of years. There were in addition some workers who worked outside of the World Trade Center after -- site after it closed in June or July 1st, 2002, but the majority, at least of the workers, had relatively short exposures. Although I'm impressed by if you worked 12- to 16-hour shifts, seven days a week for six months, that gives you a year and a half of exposure in a relatively short period of time. Nonetheless, by occupational standards, the exposures were relatively short but we've heard evidence, both from limited human epidemiology but also from animal studies, that short exposures can lead to cancer. That I think's an important part of the rationale.

I think Dr. Weaver raised an interesting point that we should explore about steeper exposure rates. Maybe that influences cancer incidence.

Another point is about synergy, which is, with so many carcinogens present, the rule in multiple carcinogens, even though it hasn't been thoroughly investigated, is that synergy seems to occur very commonly; and whether that's for PAHs, as Dr. Talaska mentioned, or Dr. Rom mentioned for asbestos, that the interaction when multiple carcinogens are present is the usual case, not the exception.

I think another point that Dr. Dement raised is there's no -- current scientific thinking is that there's no safe threshold for the carcinogenic effect in asbestos or for that matter other human carcinogens as well.

A further point is that the hallmark of nonmalignant disease among responders and community residents has been inflammation, inflammatory disease in the respiratory tract. And it's pretty well established, and Dr. Aldrich and Dr. Rom know this a lot better than I do, but that inflammation is an underlying mechanism for the development of cancer and that's become an emerging hypothesis but there's a lot of evidence in support of it.

Then finally we come to epidemiology. It's limited but I think the firefighter study is a positive study. Positive, I don't mean positive for people who have developed cancer but positive in the sense that it showed an increased risk. It didn't appear to occur accidentally and isn't readily explained, I think, by confounders; it's a modest increase in risk but it is there.

So I think when I put it all together, to me, this supports a case in favor of a reasonably strong likelihood that cancer has or will result from WTC exposures.

DR. WARD: Thank you, Steve. Leonard, Kimberly, do you know which one of you put --

DR. TRASANDE: Sure. I was third. I was third. I think Tom was first.

DR. WARD: Okay, good. Thank you, I was taking notes so I wasn't looking up. So which of you was first; do you know?

DR. ALDRICH: I guess I was.

DR. WARD: Okay.

DR. MIDDENDORF: Before you start, I just want to remind everybody, you need to hold the microphone up near your mouth for the entire time you're speaking. Otherwise the transcriptionist can't hear it, and we want to make sure that we capture everything clearly.

DR. ALDRICH: I'm sorry, I thought this was on. I was one of many authors of the fire department study. I was not the primary or secondary, I wasn't the senior author, but I do have a good bit of familiarity with that study and although it's a single study and only epidemiology so far, it does have a number of really important strengths: it was a well-controlled study with a known exposure, pretty well-known exposure, with good, maybe not perfect case finding, that means that the numerator was probably pretty close to accurate; and a known total population at risk, which means the denominator is pretty close to accurate; and furthermore it took surveillance bias and a number of other biases well into account. I would like to point out one thing that isn't clear from a cursory reading of that paper, that the cases that were found after 9/11 were not at an earlier stage on average; in fact, the stages were, if anything, slightly later-stage cancers for the post-9/11, which suggests that this was not surveillance bias that took -- that led to the higher level.

The finding was that total cancers were increased to a small degree. This is not an epidemic level increase in cancers but it was only seven years post-9/11 that were included in the data so rates may well be higher in future studies. Nonetheless the study was, did show an increase in cancer incidence, and so although it's only a single study and although it's quite preliminary, I think that there is some epidemiology that we should not ignore and so for those reasons I favor including cancers of some types in -- recommending the inclusion of cancers of some types in the health program.

DR. WARD: Thanks. Guille?

MS. MEJIA: Okay. I'm just going to jump into this. It's my position and my opinion that cancer should be covered. Whether all cancers should be covered, I

don't know. You know, that's something that we need to have further discussions on.

What do I base this on? Well, it may seem -- my rationale may seem elementary to some, I mean, I'm not a doctor, I am not a scientist, I am not a researcher, but I think it's a conclusion that any reasonable person would reach based on the presentations that we've had for the last three or four days, you know, the beginning in November to today.

We know a lot of things. Whether we can put them all together is something that we also have to work out but we know a lot of things. We know that there were lots of substances that were present in the environment and we know that many of these substances are very toxic and many of them are carcinogens.

We know how the exposures occurred. People were caught in the cloud and then there were workers who were responding and performing work that was necessary to rescue and eventually restore the area.

We know how and why these substances entered the body. I mean, right? We know the routes of entry; there was inhalation hazards. There were no controls in place so that, you know, the workers could not be protected against inhaling some of these substances or ingesting some of these substances or coming into contact with some of these substances.

We know that there are effects from these exposures based on the fact that we have workers in the program that have covered conditions. So there are some effects from these exposures. The fact when we're dealing with cancers, at least in the field of workers comp, there is -- there have been cases and causal relationships established between the disease and the work at Ground Zero. So there is some causal relationship there.

We know that, aside from many of these substances being classified as carcinogens, many of them are also -- can cause inflammation and can cause irritation that may be a precursor to cancer. All right, at least that's what I heard from the presentations.

We know that there are many gaps in the data but we should not hold that, you know, against the worker. It's not their fault that there are no -- that there is not enough data there. You know, they were just out there to respond and to take care of what they needed to take care of.

Yesterday we heard a presentation about short exposures to high concentrations of substances, especially in the textile workers. I think that's important to keep in mind, that just a short exposure can lead to cancer. So, you know, we don't need to worry about latency. I mean, the traditional thought about cancer is that there's a latency period involved. I mean, it's like an old married couple. You talk

about cancer and you got to talk about latency. In this group they don't have the luxury of time to wait.

Just a few other thoughts. Just because the association between the exposure and cancer may not be strong at this time, I don't think that we should dismiss it entirely. I think there's enough out there to make a case for the coverage of cancer.

And finally I think that what I need to say is that even though the incidence -- if we deem the incidence of cancer among the population to be improbable due to a lack of studies or any other information, I don't think that it means that it's not plausible. And that's an important point to make. That's it.

DR. WARD: Thank you. I think Glenn was next, then Kimberly.

DR. TALASKA: Okay. First of all, I would agree that I think that cancer should be covered under -- for the first responders, and I think there's several reasons. I think Steve just did a great job of very systematically laying out why, and Guille did, too, why it might be the case.

I think some of the arguments against that seemed to be important were that the epidemiological data are not strong enough for causality, and that is an argument that, again, I think, on the other hand the data are starting to show some things. And in the studies that are being done they are trending in a way that is disturbing for an observer. Second, I think the other reason that one might believe that it would not be related is that the data today report that the exposures were relatively small. I think we heard yesterday from John Dement and I provided some evidence that that may in fact not be the case and that there's reason to believe that the exposures were, for the individuals working in the Pile certainly, that the exposures were quite large. And that there are data to support that from some of the biological monitoring that was done, and also the relationship between the personal and the area samples, and the history of that.

So I think, and then most importantly I think we've got a soup of carcinogens which are known to affect several sites, specific sites, and these are some of the sites that we're considering. So the materials that were known to be in the cloud and materials that were known to be at Ground Zero have caused disease which people, some people are seeing.

And then finally that the interaction between these materials, the soup included materials that were not only carcinogen initiators but were carcinogen promoters, and they tend to complete the package. And some of these materials were those which would tend to persist.

I agree with the others on the committee that the exposure apparently, if we have people that are working for six months, working long shifts and double shifts, that

in fact that's a significant exposure and a significant time that they were there. In some cases locally extremely high levels, it appears, so I think there's, for those reasons, I would support the inclusion of at least some cancers into the, into our recommendation.

DR. WARD: Thank you. Kimberly?

MS. FLYNN: I think that some cancers, and I am not expert enough to say which, but I think certainly non-Hodgkin's lymphoma, I will never hear the initials NHL as National Hockey League ever again. This has been a constant refrain but I would certainly go beyond blood cancers. I think that some cancers must be included for the exposed population of responders and survivors.

I want to remind anyone who was not present at the November STAC meeting to hear the survivor presentation, to please go back and read that presentation in the record. Survivors were exposed in myriad, myriad ways to World Trade Center dust and smoke, some of the testimony we heard earlier today went to the fact that survivors had, you know, intense dust cloud day-of exposures, they also had ongoing exposures in the area. Many people live and work in the area, as Jo Polett testified, there is World Trade Center contamination -- was World Trade Center contamination present in air handling units in her building. This is the case in many buildings.

Everyone here needs to understand that there was no proper testing and clean-up program by the Environmental Protection Agency, the only agency that in fact has the expertise, obligation and capacity to pull off such a program.

Fewer than 18 percent of apartment, individual apartments in lower Manhattan below Canal Street, were cleaned by the EPA. And there's a lot of people here who could tell you that in many ways that clean-up was flawed and inadequate. So, you know, when a cancer is added for responders, it's added for survivors under Zadroga for that reason and also for the reasons that survivors do not have a monitoring program.

Responders have a monitoring program. You qualified for that program if you were exposed. Survivors had a treatment program which became widely available to them in the year 2006, very, very late in the game. Lots and lots of survivors went elsewhere, saw private doctors. That is one of the reasons why the denominator, the number of patients in the survivor program is, you know, a little over, well is probably closer, actually at this point, to 6,000.

But shifting on to some of the testimony that we heard today and also a repeated refrain, which I think is very, very important, that the events were unprecedented, that the exposures were unprecedented. And I guess I want to challenge all of the experts on this panel to really very carefully think through what that means in

terms of constructing a robust rationale for cancers to be added. And I think that actually that Dr. Markowitz and Dr. Weaver have started doing that.

So unprecedented means that you are exposed to a host of toxic materials which are simultaneously carcinogenic, mutagenic, materials that simultaneously attack the nervous system, the immune system, the endocrine system; and that for many, many people these contaminants, their exposure to these contaminants, was in the form of an absolutely unprecedented assault. I had firefighters tell me that being in the vicinity, being on the site, when those buildings collapsed was like having somebody pull your head back, open your mouth and, like, load in, you know, three bottles of talcum powder, you know, at 150 miles an hour traveling into your mouth and overwhelming your airway, overwhelming your body systems and I'm not excluding cops, who we know were exposed and had no respirators. We know so many people had no protection whatsoever, but I'm saying that the insult to the body was absolutely unprecedented.

I'm saying also that these insults happen in ways that we know about because we saw them on television and they happened in ways that we don't know about, so I'm talking about, you know, as Dr. Weaver said yesterday, the toddler crawling on a contaminated carpet, the kids who were jumping up and down on a contaminated sofa. I mean, these things happened all over lower Manhattan and in fact we really do not have any idea whether or not there are still people living and working in the area who are subject to ongoing exposures from the fact that, for instance, the air handling units were never properly cleaned.

The other piece of this unprecedented -- so you have unprecedented exposures, you have unprecedented, you know, unfathomable exposure scenarios, some of which are ongoing, and likely ongoing, it's reasonable to assume that, and you also have this sort of new kinds of illness. So the medical director for the survivor program, **[identifying information redacted]**, has said many times -- I think she's also testified to this in Congress -- that we're treating it, we're treating World Trade Center asthma like regular asthma but really we don't know what it is. So there are ways in which the disease process and there are ways in which the kind of the end point illness is WTC-specific, and I think that's also something that the experts here really need to take into account.

What are all of the ways in which these unprecedented exposures may be shortening latency times? What are the ways -- I mean, I thought the idea that Dr. Weaver had, that we're looking at the possible impact of steepness of exposures. What are the ways in which we're seeing people who should not be getting multiple myeloma showing up with multiple myeloma in their early and mid-40s? What about these rare cancers that we're hearing about?

And I guess when we start to look at the epidemiological record, I would have to remind everyone here about Micki Siegel de Hernandez's testimony and the degree to which what we currently have by way of, you know, denominators and numerators is a partial perspective.

There are so many people out in the country right now who are not, whose cancers are not being counted in the monitoring program, whose cancers are not eligible for the World Trade Center health registry or maybe they didn't even know that the World Trade Center health registry existed. So there are all of those people out there and some of them actually managed to make it in here and talk to us.

So I think that we, you know, we understand, you know, I think that the FDNY study was very well designed and I'm very glad to hear Dr. Aldrich say that, you know, he considers it to be strong, strong epidemiological evidence, and as a non-expert, I wholeheartedly agree. I understand also that the FDNY needed to take certain steps to be able to say that look, we're controlling for surveillance bias. I understand that but we also need to consider, as Micki said, the numbers of people who are not being surveilled at all.

And I think that we have to base our considerations -- and it's very, very reasonable for us to make sure that we are not allowing this, this population to essentially fall into a data gap that was not created by them and that is not their fault and I think that we owe everyone, survivors as well as responders, deliberation here that looks at the available data in the context of unprecedented.

DR. WARD: Thank you, and I've tried to now make a list of tent cards 'cause we have so many of them it's hard to follow, but I think the order was Bill, Leonardo, Julia, Valerie, Susan and Catherine? So Bill.

DR. ROM: Thank you. First of all I think I would like to start off by seconding Steve's list of exposures. I do make the case that WTC dust and responders have a risk for cancer. The exposures included carcinogens, there were multiple carcinogens, there was broad exposure in the short term, and all of these increased the risk and these people will develop increased numbers of cancers.

Second of all, the issue of lumping or splitting, do we just say cancer or do we say specific cancers? I think the Zadroga Act answers that question. It doesn't just say lung disease, it lists lung diseases. So if you look through the list and you look for sarcoidosis as a specific lung disease, you don't find it. And the Zadroga Act did do a little bit of lumping and took sarcoidosis and put it under interstitial lung disease, which probably has a few diseases that may not be associated, so I guess we can do a little bit of lumping.

So going on to the specific diseases, I think lymphoma, leukemia and multiple

myeloma already are being seen. And even with such a short latency these cancers are coming up and we should probably list them. But then you get to splitting again and lymphoma has non-Hodgkin's and Hodgkin's. And you look through the firefighter paper and non-Hodgkin's is significant but Hodgkin's is not. And then if you look at leukemias, ALL occurs in children and CLL in older patients. It may not have much of a biological plausibility for environmental exposures so I'll take a pass on those, leave it as a lumping.

And then there's two big sites that are -- need to be addressed, and they're the major sites on the list you put on the board and that's lung, and then some other sites that came up positive in the epi studies. So for lung I'll start with that. That did not come up in the firefighter study and it did not come up in **[identifying information redacted]**line about the Mt. Sinai study of the responders. But I think lung is very biologically plausible, and we have the carcinogens and we are going to see lung cancer, and I think these people should be evaluated and should get support. And I would expand the lung to also include mesothelioma, even though we're violating our rule of latency on both of them as we don't have 20 years you need for lung cancer and 35 to 40 years for mesothelioma. I just don't think we can wait that long for proof.

And then there's three sites that popped up that I don't think there's any biological plausibility at all, and they're thyroid and prostate and some sites in the GI track. So these popped up in the firefighter study and **[identifying information redacted]** mention of the responder study. So I have difficulty in supporting sites that just don't have any biological plausibility for environmental exposure, WTC dust or otherwise. It just doesn't make any sense. That's too, that's a bit of a leap. And we have to provide the science to the administrator and we can't provide any science on those, other than data from these epi studies that probably represent surveillance bias and other confounding reasons they came up. And maybe the committee can address these further. Thanks.

DR. WARD: Thank you. Leonardo?

DR. TRASANDE: Thank you. I want to begin by supporting Steve and others' lines of argument and state my opinion that cancer should be included as a covered condition, leaving pending the second component of the discussion.

I wanted to add roughly five points that I think represent issues that have been glancingly addressed so far but I think are very important. One is that our legal direction, as I understand it from the Zadroga bill, is not to distinguish subpopulations, and my understanding is that we're still always relying on a clinician judgment once a condition is added to the bill for -- that is required in order to result in having a patient have care supported by the Zadroga fund.

And also my second point is that community exposures were highly variable in this context and likely overlapped in ranges of exposure with exposures experienced by many of the responders, and I think that's important to highlight and I think, much as we try to characterize those exposures with questionnaires and other methods, it may be impossible to really tease that apart very carefully. And I'm hearing a theme of well, we know in responders there's more plausibility for responders but I think there's a very large gray area here that we need to accept. And I think there's quite a lot of plausibility for community exposures leading to cancer in this population as well.

I wouldn't be here if I didn't raise a point about pediatric and perinatal vulnerability. That raises additional and worrisome concerns in what are likely less exposed populations. So that's my third comment, and I think the literature on that vulnerability is ample, I don't think I need to review it here.

I want to keep my comments brief and just proceed to my fourth point, which is that there -- we've talked about statistical capacity of the fire -- the department study of the responder study that was presented yesterday, there's extremely limited statistical power that exists, even if you use the whole 46,000 children who lived below 14th Street on September 11, 2001. That nearly eliminates the possibility of a definitive negative study in that population. And so I think I want to caution, voice my caution, that we will need to rely on plausibility and reasoning by analogy for pediatric and perinatal exposures and their association with cancers that may have even latency in the range of a 30- to 40-year range, given the uncharted waters that we're in. And though I would say it's worthy of further study and I'll leave that point there.

Following up on Bill's point, my fifth point is going to signal a concern I have about splitting cancers by category, and that's especially keen for the pediatric population. While I agree there are certain cancers that predominate and you would expect increases in patterns to emerge if they were to emerge for ALL and other conditions, and I agree with Bill's points that there are some concerns about plausibility. I am concerned that we are in, in an uncharted territory and may have to err on the side of biological plausibility as being the momenarm (ph) for our decision, and so I just would also raise further cautions when we're splitting on the basis of adult responder data. And my concern being that there will not be very good applicability of that coverage to a population that may have been affected at an earlier stage of life. Thank you.

DR. WARD: Okay. Julia?

DR. QUINT: First I do agree that cancer should be included as a covered condition for many of the reasons that Dr. Markowitz -- and I will third his notion of why.

Lots of carcinogens, many -- some human carcinogens, lots of animal carcinogens, and I want to say something about that in particular. We seem to be -- when we act as government agencies to protect workers and public health, we try to protect both populations from chemicals that have been identified as carcinogens based on animal data, and we do that by implementing regulations and policies. One of the commenters yesterday said that if he were under OSHA jurisdiction and were constructing a building and had to use many of the carcinogens that have been identified in the WTC dust and smoke, that, you know, he would have to use certain controls because we do believe that those cancers that are found in animals can cause cancer in humans. So that, you know, I think it's a false distinction on the public health side and the prevention side, when we have laws and regulations, to say that those are, those chemicals can cause cancer in humans on one side and then when we end up seeing a number of cancers, that, you know, we have a different rule for the covered conditions. You know, and in that the agencies which are tasked with identifying evidence of whether or not chemicals cause cancer, the National Toxicology Program and the International Agency for Research on Cancer are now classifying agents as human carcinogens based on mechanistic data in addition to epidemiological data and animal bioassay data; and in fact, benzo alpha pyrene was classified as a human carcinogen, is one of the WTC agents, is now classified as a human carcinogen by IARC where it wasn't before, and this is based on mechanistic data.

And in addition IARC has published a review in which they have identified 11 sites of cancer for which there is sufficient human evidence, and some of the -- for those 11 sites, WTC agents are implicated; in other words, if you look at, I don't know how many of the different agents, but asbestos for instance, they have said that there is sufficient evidence of human cancer for cancer of the ovary for asbestos.

So I think we should definitely look at that IARC review in terms of the cancers that they have had -- have deemed as sufficient evidence of human cancer for the agents that were in the WTC dust and smoke. Is seems very pertinent. They're a very prestigious group. But they are looking at lots of data. It's reviewed by a huge panel of people, and I don't think we need to repeat that review.

Again, you know, we talked about exposure. We don't have a lot of exposure data but we do have -- we operate on this premise, again, on the prevention side that if chemicals are genotoxic there's no safe exposure level. Many of these chemicals, most of them are genotoxic. And even for the ones that may be operating by an epigenetic mechanism, we have individual variability in terms of the exposed populations, both survivors and responders and the whole gamut of people who

were exposed, and we have different background exposures. And one of the ways in which this can play out is that some people have a very different ability to metabolize chemicals, toxic chemicals, to make them nontoxic, so that will contribute disproportionately to their risk for cancer. And we don't know a lot about that.

The other thing is we don't know how large the number is of people who may have developed cancer from these exposures because we don't have sufficient surveillance systems to pick them up. So I think that, you know, all of this is a developing science. The mechanistic data is developing as we speak. A lot of the cancers that are not deemed to be human carcinogens today will be in the future. So I personally have a very hard time.

Some cancers we have more evidence for. I would definitely go with the list of cancers that have been shown in epi studies where there is an increased risk, and definitely the ones that IARC has associated with some of the agents that we know were in the dust and smoke. But beyond that we don't know which cancers in humans will be caused by the chemicals that cause cancer in animals because they aren't concordant. And so I think that that raises the possibility that some of these cancers that we don't think -- that we don't have evidence for now, we might have evidence for in the future based on mechanistic data, and I have a very hard time leaving, you know, saying that cancers that -- for which we don't have human data right now and don't have strong biological plausibility may not be covered. That's my dilemma with all of this.

DR. WARD: Valerie.

MS. DABAS: I also looked at the IARC report and I found several things. One of them was ovary cancer linked to asbestos as well as larynx, colorectum, stomach. They also identified beryllium now as a human carcinogen and found that there was significant epidemiological studies that indicate a high risk of lung cancer in occupational group. Cadmium also had carcinogenic levels. On page 80 it identified prostate cancer as one of the things that it was -- that it linked to it. Urinary and kidney cancer were amongst the ones that they found. They identified lead and that it increased the risk of lung cancer, stomach cancer, urinary bladder cancer. When they looked at PCBs and they found Hodgkin's lymphoma in one study dated 1996 as one of the risks of being exposed to lead. Again, quoting from them, as in the studies reviewed by IARC, instead of risk of liver or bile duct cancers were reported in several cohorts and follow-up studies of capacity workers. One case control study also reported increased risk of bile duct cancer. They listed several others such as tissue sites such as gastrointestinal tract, brain, testes or skin.

When they looked at PNAs, they listed in animals that they found PNAs cause numerous types of cancers in animals including lung tumors, liver cancers, skin tumors, urinary bladder cancer, forestomach tumors, esophageal tumors, intestinal tumors, mammary gland tumors, nose tumors, larynx, pharynx, lymphoma, tongue tumors, anus tumors, cervix tumors, abdominal tumors, tumors of the blood vessels, kidney cancer, respiratory system cancer, ovarian tumors, cancers of the oral cavity and cancer at the injection site sarcoma.

So when we looked at that report we found that there was significant evidence and they had significant epidemiological studies to back their evidence in their 2011 report. I think it would be very dangerous if we start picking apart cancers, specifically for the person that came in today that had a very rare cancer. You know, what do we do with that person? Do they stay out for the entire time while they figure out whether his cancer specifically is linked to the World Trade Center exposures or what? And those people are the ones that are going to get drugs that are not covered by their health insurance. People with very rare cancers are under -- you know, they more than likely will not have drugs that, you know, are covered by their insurance.

You know, I had one guy, **[identifying information redacted]**, who spoke to me, and he has a very rare cancer of the pancreas and his drug is a test. And so it's $12,000 per month and it is not covered under his health insurance. So I think if we start picking cancers apart, we're going to leave the people that are most needy out to dry.

DR. WARD: Thank you. Susan?

MS. SIDEL: Thank you. I of course definitely think that cancer should be included and I think that, to make a case for this scientifically, I think that we're in fairly good shape because I think that one of the big things that has come out of this is that so much of the information we have is not like, it's not working in real time. Because even any of the studies that have been done, including the one that isn't even out yet, is already old. By the time they compile the people that have cancer and then match that against the New York state registry, which is two years behind, and then they have to submit it for publication. And then I'm sure the publication period, you know, that takes awhile because you might get rejected; you have to go some place else, and then your article has revisions, so anything that we can work with in real time is going to be way too old for it to be, to help people today.

The other thing that I'm very concerned about is that our committee and in fact the entire World Trade Center health program is over like 15 years from 9/11, right? There's, like, a statutory end to this. And that is when we're going to see --

that is when we are going to have the latency period for a lot of cancers come up, so if we did rely on epidemiological studies, we're not going to have them until we can't do anything with them. And that is really, really hard, you know, that is a shame.

I think that there's a lot of information in the articles we do have. On page 904 of the fire department, **[identifying information redacted]** article, in the first paragraph, I mean, the first column, I think it's the second paragraph, where he's talking about inflammation and how other diseases of inflammation that are affecting survivors and responders are the diseases that are covered, so that's like a big lead-in to what kind of cancers should -- you know, if you follow the same thinking, the same track, I think it's going to just naturally take you to covering certain cancers.

And then the other thing is that we have a lot of information that's just old established science on what carcinogens cause when people are exposed to them. And I think that it's out there, it's old established science and that we can just compile things based on that evidence. Thanks.

DR. WARD: Thank you, so what we're going to do is take the final comments, like, from Catherine and Bob and then we'll take a break for lunch.

MS. HUGHES: Hi. As I think the only local mom on this committee, I just wanted to provide a little insight 'cause I had two young boys on September 11th. And people talked about exterior clean-up. Well, one of the problems was the EPA was supposed to be in charge of the internal clean-up on spaces and then the DEP was responsible for the outside.

And every part of it was a process and we've heard about whether it's worked or it hasn't worked. But for example, finally the DEP did get around to requiring that roofs of buildings had to be cleaned. For a very long time roofs were never cleaned. And facades of buildings were hosed down, if they were cleaned, for months or up to over a year. So in the summer of 2006, if I hadn't reported into the DEP clean-up, the newspaper stand one block from the World Trade Center site, then the little top of that stand would never have been cleaned. They found six bags of World Trade Center debris over a year later on the roof of the newsstand. And a lot of people walk in that area.

When I had my son's birthday in October of 2002, which was over a year, in the dark, I see a guy in a white tie-back suit with rubber boots, bolted onto the roof, doing an asbestos or EPA, you know, exterior clean-up. So I just want to remind people about the inconsistencies of exposures, and they were ongoing for the community as well.

I agree with a lot of what our medical experts have said here and, you know, that

Dr. Markowitz had kicked off, and if we could also look at cancers so we're looking at systems rather than just picking one. Because that rare cancer we heard about, I'm not a doctor but it could have been related to dioxin exposures or from the dielectric fluid, I believe, 'cause I happened to be researching it the other day, but he should not be left. So if we're looking at systems, so it could be that you were exposed through the skin, so look at the skin as a holistic mechanism, look at the inhalation and the ingestion, so that's how we can start looking at the cancers. Thank you.

DR. WARD: Thank you. Bob?

DR. HARRISON: I agree, yes. I think everybody -- I've just been taking notes. So I'm a yes also in terms of the general inclusion of cancer but I had just -- I would add just a few other points.

I think there's some interesting evidence in terms of short-term exposure to benzene and hematopoietic malignancies that could be cited as evidence. As has been said, this is a relatively short-term exposure but there's some -- quite a bit of data, I think, is emerging on low-dose and/or intermittent exposures to benzene that could provide some, you know, additional biological bases to argue that there's scientific evidence to make a recommendation.

I would like to see somehow mention of certain premalignant hematopoietic disorders. The healthcare providers may see somebody with aplastic anemia, there's a premyeloma condition, there's myelodysplasia, there's number of blood disorders that, followed long enough, will lead to malignancy without the diagnosis yet of AML or multiple myeloma. So somehow I'd like to get across that, so it doesn't hamstring the healthcare provider in not being able to provide treatment for those conditions. Sometimes it's just monitoring.

Third is I think we should acknowledge that cancer is multifactorial, that there are individuals who develop cancer from multiple risk factors both environmental, occupational and personal. I think it's important to acknowledge, for credibility actually, that cancer is multifactorial, that not all cancer is the same, that we're going to have individuals who are eligible for treatment and compensation who have smoked for 40-pack years, who have dietary risks, who have genetic risk factors, and that to the casual reader I think it's not necessarily intuitive that -- or how three months of exposure is responsible for their cancer when they might have multiple other risk factors that seemingly are even more important.

This is a problem I face all the time with my patients who have occupational or environmental exposures, and so I would suggest adding something along the lines of, I think to echo what Dr. Markowitz says, that citing the abundant medical and scientific literature that acknowledges that environmental and occupational

exposures are an important cause of cancer, that the exposures from the World Trade Center are likely to be a significant factor, or if you'd like, a substantial factor, in causing certain cancer types. So this really acknowledges that cancer is multifactorial but the contribution of the World Trade Center is a significant factor.

I think that might help the clinician, frankly, in the second phase, where each of the diseases must be certified. I think that would give them clear guidance and might give NIOSH some context in which to understand a specific case.

My last point is childhood cancers, and Dr. Rom mentioned ALL, which although I would like further discussion whether ALL should be included for adults, what about the child, you know, in the community who's diagnosed by a pediatrician, who's eligible and who has ALL? Should we not include that as a covered condition as one of the most common causes of childhood cancer? So I just want to make sure that we address that issue in some way.

MS. HUGHES: So can I make one point of clarification? I actually, I was actually looking at the New York State Data Registry from 2008. That was online, and, you know, it's four years later, and just did a really preliminary, nonscientific report and broke it down by ZIP code, and it turned out, just for lung and bronchial cancer for the years 2002 and 2006, you know, I haven't verified this, but if you look for the breakdown, there was an increase between 15 to 49 percent of above expected cancer rate for the ZIP code 10282. In ZIP code 10007 within 15 percent expected, within the ZIP code 10038, which is east of the World Trade Center site, 15 to 49 percent increased, more in the financial area, ZIP code 10005, very sparse data, and then in ZIP code 10280, you know, there was again some lung cancer, but this is just very preliminary so it's, you know, just something to think about. Thank you.

DR. WARD: Thank you. So we will break for lunch. We're back on schedule so we'll reconvene at 12:45.

(Recess for lunch, 12:02 p.m. to 1:04 p.m.)

DR. WARD: Would the committee members please take their seats so we can get started? Okay, if everybody would take their seats so we can see who's here and who's not here. So we're still short a few committee members, Paul.

DR. MIDDENDORF: Yeah, we do have a quorum, though.

DR. WARD: Okay, so we do have a quorum, and what we're planning to do is really resume where we left off and have all the committee members who haven't spoken on the main issue have an opportunity to speak, and then move onto the next phase of the discussion. So Steve, would you like to start?

MR. CASSIDY: Yeah. Thank you. You know, I want to start off by saying that I too

support that cancers be included. I think the discussion of how we decide if we limit which cancers are covered or we try to eliminate certain cancers and say they shouldn't be covered is difficult.

When I look back at what was said yesterday, some of the testimony, I thought that it was very interesting, the presentation that Dr. Rom made about burnt particulate matter and how particulate matter clearly causes cancers and that burnt particulate matter was something he really hadn't experienced before. And we didn't have any real comparisons to that. And I think, you know, when you add that to what Dr. Talaska testified to about the exposure, about the pyrenes, about how the exposure was clearly greater than was measured, when you look at what the testimony from Dr. Dement about the asbestos and just about how much was in the air in terms of the concrete dust, I think it's just clear that this episode was something that is not comparable to anything in the past.

You know, I will point to something outside of the scientific things and think about what the New York City fire chiefs, the most experienced people in the world, did that day; they never thought those two buildings were coming down. The reason they never thought they were coming down was because they weren't supposed to come down. They are fireproof, high-rise buildings. We have fought thousands and thousands of fires in high-rise, fireproof buildings. So they did not believe that they would come down maybe at all and certainly not early.

When they came down, then you look back and say well, what was different? Well, what was different was two planes crashed into them at 600 miles an hour, jet fuel, all the things that we had never experienced. And I think that highlights for us on the committee that what we're dealing with, now in terms of trying to analyze the data and the cancers that have popped up, and we're doing it with only a short period of time, **[identifying information redacted]** study, the fire department study's only seven years; that when you look at that, you have to do it in the context that this is probably a once in a lifetime occurrence. It's certainly nothing to compare to. Uncomparable. There's nothing like it so I think when we decide on cancers, I think the consensus is yes, cancers have to be covered. You know, right now I would say I'm leaning toward saying that it's impossible, or very, very difficult, to say we should eliminate these cancers from the list or that we can, as we heard testimony from people here this morning who have incredibly rare cancers, how do you say well, we don't have any data that proves that that rare cancer is likely to happen and therefore you're out. I don't know how we do that; and I think there is enough scientific data that suggests that this exposure that people suffered was unlike any other one and because of that, I think that we could make an argument that maybe we should just include all cancers.

But I certainly believe that, you know, we're going in the right direction. I think cancers have to be covered. And I'm open to further discussion about how we do that but I want to do it in the context of reminding everyone that I think that the data shows and the testimony that we've had and the doctors who have made presentations to us are highlighting that the exposures that everybody faced that went down there are unique and significant and unlike probably anything else anybody has ever faced, and I think that's why we're facing such unique problems at this point in time. Thank you.

DR. WARD: Carol?

DR. NORTH: Thank you. I'll just be brief because it's been said. I'm in agreement with the other folks around the room that it seems appropriate to include cancers. I do want to say that we've heard a number of really moving and compelling testimonials that help bring a face to the diseases and the suffering, which has been a good thing. But I want to say that I make every effort to base my decision on science and I think we have good evidence in science both in the epidemiology and the biological plausibility of the known exposures that several of the other experts in the room have summarized very well. But that evidence leads me to believe that there is a substantial likelihood of excessive occurrence of cancers without sufficient compelling arguments of other explanations.

DR. WARD: Thank you. So I think we've heard from everyone on the committee. Virginia and John, are you still there?

DR. DEMENT: Yes, I'm still here.

DR. WARD: Thank you. And I think Virginia may have left for her class. So essentially what I heard pretty much, well, from every member of the committee is that they think cancer should be included, that there's a substantial likelihood of excess risk. I think many people made very, you know, compelling and convincing arguments of that. So the issue -- so that issue seems to be everyone has a common opinion on that.

I think the question then is between the decision to include all cancers and several people have spoken to, you know, to the fact that it's difficult to decide which cancers to exclude or that it's not appropriate to exclude any cancers. Other people have spoken to the idea that some cancers are much more likely than others and so we should try to designate certain cancers or organ systems as on the list and not necessarily include all cancers.

So my personal opinion, just I realize I haven't said it, is I'm in full agreement with everyone who said that cancer should be listed, and I still have some questions in my own mind about all cancers or selected cancers. And the one piece of information that is in my mind, and I know everyone's aware of it, but I think that

one of the things that's difficult for me is knowing that, over a lifetime, up to half of men and a third of women will get cancer. So even if the World Trade Center exposed populations had not had these exposures, you would expect a large number of people to get cancer. And so that's one of the things that's in my mind that makes it a little bit more difficult to decide if we should list all cancers or selected cancers, but I do agree with some of those arguments that we know something but we don't know everything, and so yes, it's possible to say well, if it's a cancer that's caused by asbestos, then it would -- there would be a very clear rationale for including it or if there's a cancer in a site where we've seen chronic irritation and inflammation, there's a clear rationale.

But, you know, again, I see the opposite, I mean, I see the other side as well that it's, you know, it's hard to exclude any cancers 'cause we really don't have a full set of information to make strong decisions about exclusion, so with that I'd like to leave the floor open to people who have opinions one way or the other on the issue of listing all or listing selected cancers.

DR. ALDRICH: I guess others have made this point but I think it bears repeating that other conditions that are covered under the bill, certainly bronchitis and asthma, PTSD and GERD, they all occur in many, many people absent World Trade Center exposure and yet they're covered. Nonetheless I think you make a good point that there is no way to know the exact causation or whether somebody who has a cancer was destined to get it in the absence of World Trade Center, but we have to work with what we have.

DR. HARRISON: Oh, I'm sorry. I think that there are some cancers for which the biological plausibility, the tox, the animal, the mechanistic, the human data are stronger for a connection and other cancers for which it's weaker or absent, and that I would like to see our committee make a recommendation that reflects the variety or the spectrum of evidence with some suggestion, and I'm not sure of the language with which to phrase this, but some suggestion that the evidence is stronger or that we see evidence for certain types of cancer that's greater than other types of cancer, and maybe not make a definitive recommendation on which absolutely to cover; in other words, transmit that notion, but I don't want to be so crass as to punt it back to Dr. Howard to make a final determination. The alternative would be to specify and to spell out very distinctly and create a list. I guess I don't personally feel like we either have the time or the charge as a committee to review the kinds of evidence in the detail that we need to really create such a specific list.

DR. WARD: Okay, any other comments on this? Steve? Sorry, Susan.

MS. SIDEL: Hi, I was just wondering if --

DR. MIDDENDORF: Before you start, could I do one thing? The reason we have the buzzing is because the microphones have to be turned up to make sure that you can be heard. If everybody will make sure that they put the microphone right in front of their face for the entire time they're talking, we can turn that down and hopefully get rid of the buzz.

MS. SIDEL: Okay, how's that? Thank you. You know, I was wondering from a practical perspective how specific we have to be because if we say cancer then -- and maybe some other people can help with what the process is, but then your doctor, I'm assuming your World Trade Center doctor, has to say that you have a World Trade Center-related cancer. Then he's going to send that to the feds, they're going to certify it. Then you're going to have a fight with workers comp or whoever is going to pay for part of whatever. So there's a whole process that's involved.

So maybe we can lay out some guidelines and say there's certain cancers that are well-known to be associated with the carcinogens that were at the site and here's some of those, but that we're leaving it open. So therefore if your doctor can make a biological plausibility argument.

But then I'm also wondering is that in the course of that like what if, you know, do you have your occupational medicine doctor do that, do you have your oncologist do that? Who does that? So that's another thing that's out there. But I'm just wondering like in the real world how specific this is going to have to be at this point.

DR. WARD: Steven, then Kimberly.

DR. MARKOWITZ: So just to answer Susan's specific question, in the real world, the World Trade Center health program has many doctors who are not even trained in occupational medicine, and certainly not in oncology, and will be looking for a lot of guidance on what's related to the World Trade Center or not in terms of particular cancers. Whatever they decide then has to be reviewed by NIOSH which has already asked us for guidance from this committee. The more we comment on this probably the better off everybody is.

When I think about this issue I think, well, we should rely, there are various approaches. One way is to think that to rely primarily on epidemiology 'cause after all that's, you know, that's the human outcome. The problem with that of course is that we have one epi study, we have the Mt. Sinai study which we don't have because all we have is a one-liner on that so we can't really say anything about that. But whatever we say, you know, the Sinai study will be available in a couple of months and we have to leave open to whatever new findings they may have. But if we were to rely on the epidemiology, specifically the firefighter study,

the cancers we would come up with are thyroid, non-Hodgkin's lymphoma, maybe colon, maybe stomach and melanoma. That's the list and I may be, you know, overlooking one or two, depending how you interpret the numbers actually, but that's the -- that would be the list.

An alternative approach would be, I think what has been discussed, which is it look at the roots of exposure and biological plausibility and look at where the nonmalignant disease is occurring among WTC survivors and responders, and then we'd look very much at respiratory cancers, upper respiratory cancers; we'd look at head and neck, pharyngeal, nasal, sinus cancers, laryngeal cancers. And the esophageal cancer because we know that reflux is increased among responders, and maybe skin cancer because all those PAHs got on people's skin when they worked down there. And that list, actually that list is virtually completely different from the list that you construct from the firefighters' study from the available epidemiology which is an odd problem.

Another approach would be, and I think this is kind of the broadest approach, is to look at the total list of chemicals that NIOSH in their first report on carcinogens listed as being of concern, it's in Appendix E or Appendix D of that report, and there are 287 chemicals. And I counted the number of IARC carcinogens, it's either A, or one or two carcinogens, but one is definite, two is -- 2A, 2B are possible, probable, and there are about 70 carcinogens on that list. So you could take that list of 70, and IARC has nicely spent the last few years updating that list and specific sites attached to that list, and then you can match up that list with those sites, including the sufficient evidence and the limited evidence, and you'd come up with a big universe of cancers that are plausibly related to what I told you has occurred down there.

There would probably still be some exceptions. It wouldn't include all cancers. I'm not sure that everything down -- if you match that up, which I haven't done, there are probably still a few cancer types that are excluded but it would be the broadest possible list that you could cite a rationale for.

I don't know which approach we should take but I think that sort of is -- or we could, you know, say we can't decide that, in the absence of being able to decide, then just include them all.

DR. MIDDENDORF: I just want to point out to the committee that the document similar to what you are suggesting has already been developed. It was sent out to each of the committee members roughly a few weeks ago. And I think that's the document that Valerie was discussing earlier.

DR. MARKOWITZ: And does it have the cancer sites attached to that?

DR. MIDDENDORF: Yes.

DR. MARKOWITZ: Oh, okay.

DR. TALASKA: Yeah, I've been using that document for the last little while while listening to testimony and coming up with some of the sites and some of the compounds that are associated with it; and it for example in the discussion that we had for respiratory disease, clearly asbestos, PAH for hematopoietic cancer that are on our list, would be butadiene and PCBs. For non-Hodgkin's lymphoma, PAH is butadiene, formaldehyde, silica and dioxin. From leukemia, benzene, butadiene, formaldehyde, soot, PAHs and PCBs. And for thyroid the ones that are on there are dioxins, in furans and butadiene.

DR. WARD: Julia?

DR. QUINT: I also did what Dr. Markowitz did, is I counted up all the carcinogens and all of the IARC 1s and 2As and 2Bs and got 70. And I was alluding to what you said exactly in my earlier, not so articulate discussion of using the IARC list as a guide to deciding which cancers and I think Valerie actually had a broader list than I did. They have sufficient and limited. I only said the 11 cancer sites were the sufficient evidence, but we could definitely do the limited as well, and would be a broader number. So I very much favor that as opposed to any of the other two alternatives he listed, which was epi data and I forgot what the other ones were. Either that or all would be my suggestion.

DR. WARD: Let me just ask one question for clarification. So are you referring to both animal and human sites or just human sites?

DR. QUINT: I was referring to human sites. I think, and I had even narrowed it further to sufficient in human, which is a much narrower list. But I would be in favor of, you know, broadening that to the limited evidence as well. And it's this paper by Jim, right?

DR. WARD: Right. Well, there's two separate documents. There's a paper by Jim and then there's a document that Paul put together that's much longer.

DR. QUINT: That one I didn't get.

DR. WARD: That actually lists all the sites in animals as well as humans. But what it doesn't have is -- what Jim's paper has that's unique is it has the carcinogens associated with each site.

DR. QUINT: Exactly.

DR. WARD: But this, but Paul's more extensive document has the sites associated with each --

DR. QUINT: Okay. I didn't get Paul's document. And the only thing I would say about the animal sites is that there's lack of concordance with human sites, so I think we have to be a little careful about that. Because it causes cancer in one site in animals doesn't mean that it's going to cause that same cancer in humans, so I

would use caution with that.
DR. WARD: Yeah, I agree and I think that's, but I wanted to make sure that's what you were thinking as well.
DR. QUINT: Yes.
DR. WARD: Kimberly.
MS. FLYNN: I don't want to interrupt this particular flow of conversation; I just want to say two things. Would it be possible for both those documents to just quickly be resent to everybody because I'm hearing a little bit that not everyone has one or another of those documents?
DR. MIDDENDORF: I just sent the NIOSH summary out to everybody. And you want the Cogliano?
MS. FLYNN: Yeah.
DR. MIDDENDORF: Okay, yeah, I'll send that one right now.
DR. WARD: And we can even put the Cogliano up on the screen.
DR. MIDDENDORF: Yeah. We can even put the NIOSH one up, too.
MS. FLYNN: The other issue is just something I want to mark and then we can come back to it later. As I understand it, and as the AFL-CIO understands it, there is provision in the Zadroga Bill for an individual's physician to petition the World Trade Center program administrator for inclusion of that specific case of cancer, you know, based on the specific argument that would be made.
Maybe we can come back to this later, Dori. I don't know if you're the person to whom this question should be addressed but this is just in response to a point that Susan had raised. But again, I don't want to really, I don't want to interrupt the flow at this point.
DR. WARD: So as I'm hearing it, there's at least three options on the table which are not mutually exclusive. One is to focus on the limited epidemiologic study, the cancers that have been seen to be in excess in the published epidemiologic study. One is to focus on cancers basically based on routes of exposure, biologic plausibility and the sites where we've observed nonmalignant conditions. Third is to really rely on the evidence that's been assembled by IARC regarding sites of cancer associated with carcinogens that were present at the World Trade Center site, and that idea would include both sites that were deemed to be sufficient and limited in humans.
So I wonder if anyone else has a different point or a different idea than those three? I mean, obviously the other option on the table is to just specify all cancers and leave it up to the judgment of the physician.
DR. ALDRICH: Well, then you could also look at combinations of those approaches but the one big, big problem with just looking at the epidemiologic data is that

this was male only, and so clearly there would be no ovarian carcinomas, and there's a question about asbestos relationship with that. And there will be very, very few or very little possibility for breast cancer so I think that would be a problem to rely on that alone.

DR. WARD: Valerie?

MS. DABAS: I think that's why I think we leave it up to the individual physicians. I've seen them, it's, you know, on the basis that I've seen physicians specifically tell responders that their particular cancer is not linked to WTC, so it's not a far stretch to believe that physicians, individual physicians, would tell their patients that these are the reasons why their cancer may not be linked. And so if they have to make a written request to the program to get it, you know, to get this person admitted into the program for cancer, I think that they would do it with caution and we do have to leave the treating physician some leeway to make determinations for their patients because they're going to know that patient's background, that patient's, not necessarily exposure but other risk factors that may be associated that might have made them more likely than not to get cancer from the World Trade Center exposures.

DR. WARD: Tom? Did you have a comment?

DR. ALDRICH: Just one comment. I think it's dangerous to give individual treating physicians too much power in this situation. I think we see that with the Long Island Railroad disability problem. I mean, those, all those doctors verified disability.

DR. WARD: Yeah, I guess as an epidemiologist, I think I probably have more of a skeptical view of the information that clinicians would have available to them to make those determinations, and I do think we have a few people who see patients and make, you know, comp recommendations in the room and maybe they can speak to it as well but for your, I mean, one of the complications, I think, is that most occupational cancers are difficult to distinguish from non-occupational, at least based on pathology or symptoms or really anything about them, and so in the absence of epidemiologic data or, you know, other strong -- it's going to be a hard call from -- for the physician to make that determination, I would imagine.

MS. DABAS: But on some instances at the NYPD and FDNY, they have had to. When they filed for three-quarter pension disability, physicians have been asked to make that type of determination and further their determination is looked at by their district surgeon which is hired by the City, so there is some scrutiny to what these physicians are doing and I think that again, if we believe that cancer has -- there are multiple sources and multiple things that contribute to somebody developing cancer, such as their past history, then we have to, in a certain way,

also bring the physician in because if somebody has, you know, a history of -- has some type of medical history since 9/11 where they're getting treated for GERD and they're getting treated for asthma and they're getting treated for all these other things, and they develop a cancer, I think that physician can make the determination that their cancer might have, more likely than not, is caused by the inflammation from those diseases and thus World Trade Center-related.

DR. MIDDENDORF: I do think I need to caution the committee that the question before you is not whether or not you can push the determination downstream. The question before the committee is: Do you believe that all cancers or a specific type of cancer should be added to the covered list and what is the scientific justification for that? Pushing it downstream is not something that you really need to be thinking about or focusing on.

DR. DEMENT: This is John Dement, can I just interject a comment?

DR. WARD: Yes.

DR. DEMENT: With regard to the comment previously about asbestos and ovarian cancer, that's based actually on human data. The original listing in IARC for lung and mesothelioma did not include ovarian but these data came about later and is now listed based on human data as well as the larynx.

I guess I, as a researcher, favor a list based on the IARC criteria that we discussed as opposed to all cancers. I think it's much more defensible. And I too have a lot of concerns about placing too much, too much weight on physicians who may or may not have training to make these determinations.

DR. WARD: Thank you, John.

DR. TALASKA: I would agree with that very much. I think that we help the administrator much more if we can give the list of either sites or -- that have biological plausibility with related to the exposures that we know occurred, and that would help them make much stronger and much more defensible case in the political realm or any other realm. The stronger the evidence that we can provide for particular things. We have already admitted there's limitations of what's out there. And we're acting on the -- but we have seen that there is other information that we can use based upon exposure, based upon effects and relationships that are known either through human studies with previous exposures or through strong animal evidence where things like soots, where there seems to be an indication. And I think we help much more and build a much more defensible case by doing some culling and not just allowing individuals to be able to -- physicians particularly be able to -- they can say which diseases.

DR. WARD: So it sounds like several people have spoken in support of the idea of using the IARC carcinogen list. Would anyone else like to speak either in favor of

that or as opposed to it?
UNIDENTIFIED SPEAKER: I'm sorry, I couldn't hear you.
DR. WARD: Oh, I'm sorry. I was saying that several people had spoken in favor of using the IARC list, you know, the list of carcinogens that were present in relation to the IARC list of sites affected to make a recommendation, and I just wanted to know if anyone on the committee either wanted to speak -- further speak in favor of that idea or speak against it.
MS. MEJIA: Can I just make a comment? I mean, I just got this article so I really haven't had the time to look at it, but I'm uncomfortable carving out certain cancers over others.
In light of what Dr. Aldrich said, you know, we still have some questions about cancers in men and in woman and in children and in others, and again, I think that there will be controls and guidelines built into this at the other end that could then address, you know, whether that cancer should be covered or not. You know, I'm just uncomfortable about carving out and then leaving out a population that really should have been covered. Those rare cancers that Valerie spoke of, I don't want to play God here.
DR. WARD: Steve?
DR. MARKOWITZ: Well, you know, I think if we recommend a scheme, whatever scheme we recommend, that rare cancers should be included because they're rare and we have no way of proving or disproving, never will have any way most likely or hopefully they will remain rare, so I think they should just be included. One vulnerability of the approach -- I think the IARC approach that I'm a little concerned about is this master list of 287 chemicals which are, as we see on the title up there, chemicals of potential concern, which NIOSH inherited from 2003 proc- -- 2002 process, where these agents were assembled from EPA data from four sources. And the vulnerability is that there's the word potential concern. And it's a very long list. Clearly there's good documentation for certain things like PAHs, asbestos, dioxin, you know, important chemicals. And there may be relatively little documentation for other agents on that list. We don't have the capacity to look at that and evaluate, select out which are important and which aren't important. But it is a vulnerability because that list is very long. And if in fact some of those exposures were truly just potential and they weren't necessarily there, then it makes the approach, it undermines the approach. That's what I'm saying.
DR. WARD: Yeah, so let me just say one thing. So in terms of the IARC list, when we talk about identifying sites associated with exposures, you're really only talking about the group 1 and 2a carcinogens, which is a much smaller list because IARC

only designates sites, human sites, for those things that are thought -- that have sufficient evidence in humans. But on the other hand that approach leaves out a large number of substances for which there may be compelling evidence of carcinogenicity in animals but just no strong and enough epidemiologic studies to demonstrate a site- specific effect.

So there's pros and cons but I think, but it is important for the committee to understand that if we did take the approach of using the sites for the IARC specified carcinogens, that that would be limited to carcinogens which IARC believes had sufficient evidence in humans because otherwise they can't specify a site.

Yes.

MS. HUGHES: I also just wanted to remind people there was a meeting early on, I remember, at the Javits Center, where a lot of the air quality data analyzed was discussed. I remember one of these sampling people might have been from the EPA, I can't remember. He was like wow, we found chemicals that we never even knew existed before. So they might not even actually make this list because we didn't know that they could have been created or formed and what their impact may be, so I just wanted to put that information out there.

DR. WARD: Okay. Paul just pointed out there's 14 group 1s. Fourteen or 15, so we're talking about a relatively small number.

DR. HARRISON: What about 2As? I'm sorry, Paul, did you count the 2As?

DR. MIDDENDORF: I can try.

DR. HARRISON: Is it possible to sort of throw up some examples? I'm getting a little confused --

DR. WARD: Can we throw up the --

DR. HARRISON: -- about what exactly we're proposing now? Right. So we're talking about using the Cogliano paper.

DR. WARD: Well, let me just say what the Cogliano paper is. So the Cogliano paper was done after IARC re-reviewed all of the compounds that had been previously assessed as group 1, so it's mostly that but he's also providing data about, I believe, 2A carcinogens. But I think the sites of cancer in humans are only listed, I believe, for the group 1s. Yeah.

So basically what they're doing is they're taking the agents that are classified as carcinogenic for humans and showing the associated cancer sites.

DR. HARRISON: And that's in table 1 and what was their proposal? So use the table 1 which has both the sufficient and the limited evidence. From the Cogliano so it's table 1 if I'm doing that correctly.

DR. WARD: Right, and just basically that's just the most, I mean, it's the most up-

to-date version of all the IARC information.
DR. HARRISON: And then to cross-walk that with the evidence for exposure from the World Trade Center site? So the chemicals would have identified a concern from the World Trade Center site. Cross-walked against table 1 and then to derive the cancer sites?
DR. TALASKA: Isn't that what your paper did though, the NIOSH paper? Didn't you do that cross-referencing already on World Trade Center sites -- excuse me, with World Trade Center exposures?
DR. MIDDENDORF: Well, what's in the NIOSH document is a listing of the -- it's an extraction from the summary paragraphs in IARC identifying what the evidence is, both human and animal. So it identifies the human sites as well as the animal sites that were looked at.
DR. TALASKA: Yeah, so for table 2 it's for limited evidence in humans, which could be because sometimes it's complex mixtures and the individual components are then listed inside of that and there's never been any human data, just one compound in PAHs for example, so there's several PAHs listed there for example. And then but then sufficient evidence of carcinogenicity in experimental animals, so if we include both table 1 and table 2, and then those have already been culled because they've been compounds which were identified at the World Trade Center.
DR. MIDDENDORF: All right, you're talking about 2 or 2A?
DR. TALASKA: I'm talking about NIOSH, in your NIOSH paper, you're the lead author, table 1, which is sufficient in table 2.
DR. MIDDENDORF: Okay. In table 1 are the group 1 IARC compounds.
DR. TALASKA: Correct.
DR. MIDDENDORF: And table 2 is group 2A.
DR. TALASKA: Two-A compounds, correct. So that takes into account some of the exposure situation and actually if we use that particular table, then we have a built-in biological and exposure plausibility.
DR. WARD: Right. So we have four tents up and we'll just go in order. So, Steve.
DR. MARKOWITZ: Just to clarify. Is the proposal to include the 2As? Two-As are probably carcinogenic in humans. Is the proposal to include the 2As? Two-As include, PCBs is a 2A; it's not a 1.
DR. MIDDENDORF: Right.
DR. MARKOWITZ: So 2As, a site is specified, I believe.
DR. MIDDENDORF: It is.
DR. MARKOWITZ: In the -- right. A cancer site is specified so we don't have that problem with animal-only data where we don't know what site it causes in

humans?
DR. MIDDENDORF: Right.
DR. MARKOWITZ: We don't have that problem with the 2As. There are only a few 2As on this list.
DR. WARD: Right, so certainly then we should include them. If the site is just -- see, I think it depends. Some things may be 2A and not have a human site because it's not based on human data but I mean, if it's classified as 2A and there is human data and there is a site specified, then I think it should be included.
DR. MARKOWITZ: I agree with that.
DR. WARD: Yeah. Julia?
DR. QUINT: I'll be brief. The only -- the other cautionary note that we should put somewhere in the recommendation is that this is ever-changing because these, you know, chemicals are being moved up based on mechanistic data so we should definitely state that this is a dynamic process within IARC and now NTP as well in terms of, you know, moving class -- reclassifications of these chemicals.
And I also wanted to ask, there's another paper from the 100 IARC monograph, 100 monograph series that was published as a separate paper and I'm wondering if that's included. If we have all of the substances from that table. It's a special report on metals, arsenic and dust in fibers. Did your list include all of those as well?
DR. WARD: I would think it should because that was one of the six subgroups of the IARC 100.
DR. QUINT: Right, and you went through the whole series. Okay. Great. Thanks.
DR. WARD: So Steve, your tent is up. Did you have...
DR. MARKOWITZ: Oh, no, I'm sorry.
DR. WARD: So it sounds like there's no disagreement that we might -- that we would want to include kind of the cross-walk between Paul's table of the substances present at the World Trade Center and the IARC group 1 and 2A carcinogens for which they're site-specified. But I think we should -- I mean, and that may cover a large number of the sites that we would be otherwise concerned with. But I guess one question would be -- so that's one approach and it's very systematic but should we also -- I mean, I'm concerned about the cancers that might be associated with the sites of chronic inflammation and irritation, whether we want to call that out specifically, and this may be getting beyond our charge but I still think it's worth having in our minds, so for some of those cancers, like laryngeal and oral pharyngeal, if they're specifically called out then there may be increased scrutiny or screening.
Now as someone who's now devoted their life more to general cancer issues, I can

say that it's not a foregone conclusion that early detection and screening is beneficial all the time. Sometimes it can just result in longer survival with the cancer and not a reduced risk of dying of the cancer, but still there's an -- yeah, it can. Unfortunately, so. So I guess but I do think it's worth, 'cause I guess in my mind still from, and it's from, you know, many of the things we discussed yesterday, I do have a particularly high concern for cancers developing at the sites where there's inflammation and irritation just because of all of the things we discussed yesterday. You've got exposure to mutagens, you've got -- and then you've got these chronic inflammatory processes that could very well enhance the potential for developing cancers at those sites, so that's one piece -- that's one question that, you know, I'd like to hear some opinions on. Glenn?

DR. TALASKA: I'm in strong -- now I'm in strong agreement with that, now that it's on. The best case for cancer synergy in the world is the interaction between aflatoxin exposure in China and the hepatitis B1. Individuals who are positive for aflatoxin exposure have about a five-fold increased risk of liver cancer and individuals with hepatitis B1, have hepatitis B, have it was like seven- or eight-fold but the interaction is 60-fold, so if you're positive for both you have a 60-fold excess risk.

And that's the idea, again, of irritation, increasing self proliferation. And I'm in full agreement with what Steve said earlier about for those sites where cancer occurs in the organ systems that are already included in the program, where there is irritation, where there is chronic exposure, where there have been effects documented I think, are -- should be really highlighted. That should be part of the biological plausibility when we say these sites, there are data from the exposure to support these sites. That should be highlighted. Where we know the exposures are high, that should be highlighted 'cause it gives the administrator much more information in defense when they come back.

The more information we can provide them, I believe, the better. And for those sites we don't know, we can include all of these other sites as -- if we want to just say we approve cancer. And then these are the ones which have this level of biological plausibility, these are the ones that have this level, this is where we don't know, from a scientific point of view, and we can help them out.

It's all we have. We just can't -- it's not really up to us at this point, I don't believe, to assign that now this is related to this, if there's no evidence at all.

DR. WARD: Yes.

DR. HARRISON: I just have a question. I agree with what you said, Liz. I just have a question about using the IARC 1 and 2A: Is that sufficiently precautionary in its approach? I just don't know enough. I just don't recall the criteria upon which

2As are developed and whether we're --

DR. WARD: No, it's not really -- I mean, because the reality is there's a lot of carcinogens on the 2B list that are, you know, are known to be carcinogenic in animals; there is not sufficient human evidence. And typically that's because there's been no opportunity to do definitive human studies. It's not that there are no -- it's not that there are negative studies, it's that there are no studies or there are small studies. But on the other hand, so if you're trying to look for sites of cancer, of potential risk from specific exposures, it's really the only, it's the only source of data because you can't specify a site at risk if you don't have human data. But it is a real limitation, and I certainly think that it's, you know, in general it's not precautionary to just look at human -- carcinogens based on human evidence.

DR. HARRISON: So are you arguing that we should include 2Bs?

DR. WARD: I don't think we can, you know, in looking at -- I mean, I think we should consider 2Bs as potentially carcinogenic but they won't be of great help in looking at sites and focusing on sites of cancer of particular risk.

Steve?

DR. MARKOWITZ: But, you know, we can make that explicit in the recommendation that we considered 2Bs and we ran into this practical problem was that they're not -- don't coincide necessarily with specific human sites but that if there's some way in which to use that information in the future or -- so is the proposal then to use IARC 1s and 2As and then supplement that with additional cancer sites for which there is epidemiological information, data or otherwise biological plausibility?

DR. WARD: I think so. I think, I mean, for sure the 1A and 2As for the sites, and then I think several people spoke strongly on the inflammation, irritation, biologic plausibility. I don't think very many people have spoken about the using the results from the epidemiologic study but certainly that's something we should consider. Yes?

DR. ROM: I just want to make sure that we're all speaking the same language. I was going back to the Cogliano article, table 1 lists the carcinogenic agents. There are a hundred things listed. And the second column says cancer sites with sufficient evidence in humans. I take that now we're all agreeing that's IARC 1. Okay, the third column says cancer sites with limited evidence in humans. I'm taking it we're all calling that 2A from IARC. Is that correct?

DR. WARD: It may not be totally exactly correct but by and large it's correct because a carcinogen can be group 1 without human -- without sufficient human epidemiologic evidence. If it has evidence in animals and it has evidence of the

mechanism in animals also being relevant in people. So that's the group 1. And 2As for the most part will have limited evidence in humans and sufficient evidence in animals, you know; in some cases where there's limited evidence in humans, they will specify a site for that.

DR. TALASKA: I think all the ones in table 1 do say they all have sites which have sufficient evidence, but then there are also sites which have limited evidence in humans, okay, so they've already been listed as 1A carcinogens because they have sufficient evidence for one site, more limited evidence for the other.

DR. ROM: Okay, this table also lists occupations so I think that we can pretty much ignore. And then it also lists many different medications and I think -- and so that's something we can ignore.

DR. WARD: And we're only focusing on the agents for which they're on the list of agents that were present at the World Trade Center site, which is pretty exhaustive. It's listing everything but you could speak to how that list was generated.

DR. MIDDENDORF: Essentially what we did was we went back and we took the list that the EPA had developed, and it wasn't just the EPA, they had some other folks with them, identified chemicals of potential concern from four different databases that they had put together. And then we also added, based on the suggestions from the committee at the last meeting in November, selected other chemical agents. I think we added soot and some other things that the committee had suggested needed to be added to that list, so we added those as well.

DR. WARD: Steve?

DR. MARKOWITZ: But Bill, there are some 2As that are in -- I don't think are in table 1. I think to get into table 1 you had to be a one.

DR. ROM: Right.

DR. MARKOWITZ: For instance, tetrachloroethylene, which is a 2A, it's perchloroethylene. And I don't see it here, but it is a 2A. It would be included if we recommended 2A.

DR. WARD: Yeah, and I think that's the proposal is 1 or 2A. As long as there's a site specified in the 2A listing, either sufficient or limited. Otherwise it could be included as a potential carcinogen but it's not informative as to site.

DR. MARKOWITZ: In looking at this list that Bill drew our attention to, there is radiation listed in the IARC and we haven't really discussed that at all. Is there any evidence that there was any exposure to radiation at the World Trade Center? Exposure?

DR. MIDDENDORF: Yeah, the limited data is reviewed in the first report, the first review of cancer, first periodic review of cancer, and my recollection is that there

is very little radiation exposure.
What was looked at, trying to remember what it was. Yeah, tritium was looked at and there may be some -- one or two others, but the general finding was that there was very little potential -- there is very little identified exposure to radiation. And by radiation I'm referring to ionizing, not non-ionizing radiation.
DR. WARD: Yeah, the one question that I had yesterday, when the results of the analysis of the uniform were presented, was that barium was listed. And I don't know enough about barium to know if it's -- I know that barium, forms of barium are used for radiologic examinations because they are radioactive, but I don't know that -- but it's not?
UNIDENTIFIED SPEAKER: No. I don't think so.
DR. WARD: Okay. Good.
MS. HUGHES: I also believe that there were medical offices at the World Trade Center site as well so that they had x-ray capabilities.
DR. TALASKA: But if the x-rays aren't turned on then there's no exposure at all, you know, unless they had a sealed source site and those are pretty well protected, pretty well. But I don't know.
UNIDENTIFIED SPEAKER: Not after an explosion.
DR. TALASKA: Yeah.
DR. WARD: So I guess one question that would be nice to have the answer to is: If we did what we're proposing to do, in terms of the IARC match, you know, are there major -- are there sites of concern that were found in the epidemiologic studies or for other reasons that would not be included, and I mean, there was a specific question about childhood cancer; we obviously have not discussed childhood cancer very much but maybe if we like that approach, then we probably should also look at what's excluded and Glenn and Tom both...
DR. TALASKA: No, all of the sites that, at least the ones that I mentioned earlier, respiratory systems, hematopoietic, non-Hodgkin's lymphoma, leukemia, and thyroid are all included in the list that was in Paul's presentations.
DR. WARD: What about prostate?
DR. TALASKA: Prostate? I don't -- let me check. Prostate'll be one I check.
DR. WARD: Tom?
DR. ALDRICH: Yeah, I was just looking that up. I didn't get to prostate but two -- what I was concerned about is thyroid and melanoma, and both of those get cross-referenced so I was just going to look up prostate and have that for you. Looks like there's some animal data linking prostate to several ones but I don't see any human data. No, I don't see any human data with prostate.
MS. DABAS: Just uniform, the barium that you found, it was from Day 1 the

uniform -- his uniform so at that point the x-ray machines hadn't gotten there so it wouldn't be likely that that's where it came from. His uniform came from being on the site on the first day and then leaving shortly after for medical attention.
MS. HUGHES: Point of clarification, I meant there were medical facilities at the World Trade Center complex. That could have had radiation in it and that could have been a possible source.
MS. DABAS: Oh.
DR. TALASKA: Prostate is one that wasn't -- there lead and cadmium are the two that are listed for prostate.
UNIDENTIFIED SPEAKER: Arsenic. And arsenic as well.
DR. TALASKA: And arsenic. Okay.
DR. WARD: So that would be included as well.
UNIDENTIFIED SPEAKER: Limited for arsenic.
DR. WARD: Yeah. Susan?
MS. SIDEL: I was just wondering if there's anything -- if we should like be comparing this list to say the list that came back from Lee on what was on that uniform just to cross-reference it?
DR. WARD: I think we can do that. I think -- I mean, like I said, I noticed that many of them seemed to be the same. The one that popped out at me as not having been on some of the other lists was barium but certainly we can, we can do -- but I guess the one caution, now that we're thinking about this approach, is that much of the data on these carcinogens that IARC used was from occupational studies and it was primarily men, so it will under-represent cancer sites that might occur predominantly in women or only in women, so that, that is an acknowledged -- it's a universal problem. Yes, it's a universal problem. But it's probably something that we would want to acknowledge.
DR. TALASKA: But Liz, we, you know, the barium that's used in medical procedures, if that's what we're worried about, is not radioactive.
DR. WARD: Well, that was my specific question.
DR. TALASKA: Yeah.
DR. WARD: Yeah.
DR. TALASKA: It not radioactive, it's used as --
DR. WARD: They make it radioactive.
DR. TALASKA: -- a radio-opaque substance.
DR. WARD: I see, gotcha, gotcha.
DR. TALASKA: Okay? Okay, so that they can trace the line of the whole --
DR. WARD: Yeah, thank you. Yeah. Thank you.
DR. QUINT: I just have a -- can I? I thought we were going to include the cancers

that had increased incidence in the epi studies along with the IARC list; is that not correct?

DR. WARD: Well, that was what I was just trying to get clarification on. We heard several people speaking in favor of the IARC and several people speaking in favor of the ones that were affected by nonmalignant diseases but only a few people had specifically said to make sure -- I mean, many of them will be covered already.

DR. QUINT: Right.

DR. WARD: But I guess even if they're covered already, we probably, in our evidence summary, would like to specifically state that there's further evidence from an epidemiologic study.

DR. QUINT: I would agree with that. I want that included as far as --

DR. WARD: Tom?

DR. ALDRICH: From the epidemiologic study, there are only a few individual cancers for which there was even a suggestion of increased cancer risk because the numbers were so small. I mean, even though it was close to 10,000 people, the numbers of cancers were small, so non-Hodgkin's lymphoma, but that's already going to be covered based on IARC; thyroid, same thing; melanoma, same thing. The only concern is prostate. And the truth is the epidemiology for prostate is pretty weak because the prostate is one of those cancers that is really, really susceptible to surveillance bias. And post-9/11, people were getting a heck of a lot more exams and blood tests detecting prostate cancer. So I'm not sure there's a clear-cut -- any clear-cut evidence of prostate cancer has increased by the events of 9/11.

Now, we heard yesterday from -- that the Sinai study may show that but, you know, we can't base anything on a few words about what a study that has not yet been published will or won't show. So I find it difficult to justify including prostate.

DR. WARD: Valerie?

MS. DABAS: I guess my question on the prostate with the fire department study is just the average age in which these people were diagnosed. You know, we can say that the number is not significant when we look at the general population but do we look at the age of these -- you know, if the average age to be tested for prostate cancer is 55 and we're getting people that are in their 40s getting prostate cancer, is that not an area for concern and do we just dismiss prostate cancer in general?

DR. ALDRICH: Among the non-exposed people in the fire department study, they were all under the age of 60 at the onset of the study. And there were a substantial number of prostate cancers, both in the exposed and unexposed

group. What was not so clear was that there was an increase. So it's not like there -- prostate was one of the ones -- one of the highest represented cancers in the unexposed group, so I think the problem isn't lack of case finding and I don't think the problem is an age issue with prostate. There may be an increased risk of prostate cancer from World Trade Center but I don't think the epidemiology is enough to show that, and we don't have any chemical, what do you call it? Chemical risk data that shows a prostate risk.

DR. WARD: I thought somebody said lead, arsenic and cadmium.

DR. ALDRICH: Did I miss that in my search? If that's the case then we don't have a problem.

DR. WARD: Yeah. Glenn?

DR. TALASKA: Yeah, the cadmium one is going to be tough because there was biological monitoring data and cadmium is one of those things which persists. So once you're exposed to cadmium, you know, your first day of exposure to cadmium -- if you're going into a job making batteries, 30 years later when you retire, you'll still have 50 percent of that first day's exposure in your body. Okay? So cadmium is one of those compounds where it leaves a long trail. So basing it just on that, I think, is a little bit weaker and will set the administrator up for a bit of criticism from it because in fact cadmium levels were lower in the firefighters than they were in the control population overall. There were a few -- there were some firefighters that had had higher levels.

DR. WARD: Susan?

MS. SIDEL: I was just going to say, the one point that I wanted to make is that maybe, you know, the other factor is considered, that is this cancer unusual in someone in this age, and so therefore it was something that wasn't going to be included, it could be included because it's affecting somebody, you know, at a time when they shouldn't be having it. If they were too young to really have this cancer so then it's more likely that it's World Trade Center-related. That could be some sort of a caveat that maybe it's not just cut and dry, that there might be some other, you know, extenuating circumstances?

DR. WARD: And I guess where I don't -- so that, would that be something that would be considered in terms of an individual clinician recommendation or is that something that we would need to make in our, in our recommendation?

MS. SIDEL: I mean, if we're thinking about excluding something, I would, I would say that we should say, however, there is this factor that we -- that if somebody is below the age of whatever, that that's unusual, it's unusual to contract this cancer at that particular age, if that's the case, with what Valerie was saying about prostate, that the people that were getting it were too young to be getting it.

DR. WARD: Julia?

DR. QUINT: One thing that might be equivalent in toxicology is the time to tumor in animals. When you treat animals with, you know, with the chemical and they get tumors earlier, that's considered significant in terms of the findings, so we may have the human equivalent of that with some of these high intense exposures over a short time period in humans. I mean, that could be plausible.

DR. WARD: Yeah. Catherine?

MS. HUGHES: I'll pass for now.

DR. HARRISON: One advantage I can see to this approach is that it eliminates the need to deal with dose. So I think we're basically would be saying that if we're using a 1 and 2a and cross-walking with the exposures from the World Trade Center, if you have one of those covered cancers, you're eligible, after review by the physician and NIOSH, for treatment and compensation. So I think that has some real advantages because it gets -- you basically, I think, skirt the issue of how long were you there for, what the exposure intensity was and maybe even a latency period, although we haven't talked about the latency period yet. And I think I support that approach for its simplicity and its precautionary principle embedded in that; although, there's a part of me which says that -- there's a little bit of discomfort I have also with that approach because, you know, basic principle for many cancers, although there's certainly no threshold for carcinogens and some concept of dose response and dose risk, which we are not, which we are maybe not acknowledging this approach somehow. But I think I'm okay with it.

I guess I just want to say I think that that's a sensible approach that affords the kind of treatment and compensation to this population that I think we've heard lots of testimony over the last couple of days that's very compelling in terms of, you know, providing the services that people need.

DR. WARD: Tom? No. Steve.

DR. MARKOWITZ: I want to make sure I understand what you're saying. That we defer questions about dose and time factors to -- we don't make any recommendation about dose and time factors?

DR. HARRISON: Correct. I'm not proposing that we make any recommendation. It's almost like a presumption. Steve, you know, like there's a --

DR. MARKOWITZ: No, no, I agree with it.

DR. HARRISON: Right. Yeah, there's a cancer presumption here that if you fall into this group and this category by some scheme, 1A, 1 plus 2A plus a cross-walk to the exposure plus biological mechanisms and the other factors that we mentioned, that you're covered.

DR. MARKOWITZ: One other comment that I have, is one way of addressing Susan's concern about age is, if we do have kind of an escape clause for rare cancers, that we could define rare as being by site or by age, and that would cover that. That leaves a lot to the discretion of the treating physician but that's okay.
DR. WARD: I guess another question that I would have about this is, is in the end, are we going to come close to covering, by this approach, all cancers anyway?
DR. MARKOWITZ: No. I don't think so. I'd have to look at the tables but I don't think so.
DR. WARD: It would be nice to -- if we could -- I don't know how quick anyone can do it 'cause I -- I mean, if we're covering, if it turns out that we were covering 90 percent then -- you don't think so?
DR. MARKOWITZ: No.
DR. WARD: Even keeping in mind that lung, breast, colorectal and prostate are probably 50 percent of all cancers. So I mean, it's probably worth looking at to see which -- I mean, it's probably a majority of cancers that will be covered when we do this tabulation, I'm guessing, so then the question is which ones will not be covered, and then the other thing I think we need to be careful of is sometimes when IARC designates sites, it may -- they may not exactly match up to the sites that we know of today -- I mean, it's not going to -- I mean, we need to be careful, when we make these final tables, that we are not inadvertently excluding sub-sites or, you know, things that really should be included conceptually.
DR. MARKOWITZ: By the way, I don't see breast cancer on this list. I'm not advocating it, I'm just saying it's a big cancer that's not on the list, as an example. Most of the cancers, if you combine 1 and 2As are the respiratory cancers and the head and neck cancers, including pharynx, nasal sinuses, GI cancers, I think thyroid and prostate, melanoma and --
DR. WARD: And leukemia.
DR. MARKOWITZ: And the blood cancers.
DR. WARD: Yeah, blood cancers.
DR. MARKOWITZ: Including lymphomas and all the leukemias. I think that's it. And bladder cancer.
DR. WARD: Yeah, and I guess that really -- at this point one of my biggest concerns still is that we're not covering women, and it's not something that we did but I mean, it's going to be problematic, I think, as this recommendation goes forward that, I mean, that that is one of the limitations of that database so we should think about how to -- if we can address that and how. Bill?
DR. ROM: I have reservations of using the IARC list and I think it goes too far. And if you take the IARC list and you start with the first item, and the first item on the

list is arsenic. We're all in pretty good agreement that if you inhale arsenic you probably have an increased risk for lung cancer. But there's also a lot of toxicology violations here. You start off with oral arsenic, and then with oral arsenic, you've got bladder, skin, liver and kidney. Now we're getting what I would say is a reach that, you know, this isn't really relevant to WTC dust exposure in our experience of what we're supposed to be recommending.

So if we are to use the IARC list, and Dr. Rom says this is a reach, I think somebody needs to go through the list and annotate this and say what's relevant and what's not relevant, and I would say that oral arsenic, on the very first line at the top of the list, is not relevant to our WTC dust exposure.

DR. WARD: See then, I would argue with you. So this is why I get so difficult 'cause I would say well, a lot of the evidence for humans in arsenic is from drinking water; and people are working on the site, they're eating, they're drinking, they're touching their lips, so people have the potential to absorb arsenic through the oral route and again, I -- yeah, so that's where you get -- it gets so hard, when you try to fine tune it too much, you're going to have a lot of differences of opinion.

DR. ROM: I would argue that if you went to Bangladesh, where you've got the highest arsenic exposures in the world, you're going to have, you know, there's going to be some increased cancers, but trying to find these sites is going to be a real challenge.

DR. WARD: Well, I think where a lot of the data comes from is epidemiologic studies in countries where there is highly arsenic contaminated water, and so you do see excess bladder cancers, for example, associated with living in areas that have high arsenic content in the water.

And the other thing is that a lot of these same sites are related to some of the other carcinogens on the list.

So I also have qualms about the IARC list and the two of them are, there is, I mean, it's not really addressing women very well and it really is only those things for which epidemiologic studies could be done, and we know that that's not the whole universe of potential carcinogens. So I do think that it should be the IARC list plus, not just the IARC list.

DR. ROM: I would counter-argue once again that somebody needs to go through this list with some judgment about medical toxicology, about the route of exposure, the quantity of exposure, because you can go to benzo(a)pyrene and we think that has always been the big carcinogen in tobacco smoke, but when you get right down to it and look at adducts and all of this, you'll find that there are other carcinogens in tobacco smoke, like petroleum, which are in other aldehydes,

that are in huge quantities and make just as many adducts. And benzo(a)pyrene may not be the carcinogen for the lung cancer. And you go to the second line and we have benzo(a)pyrene as lung, bladder and larynx, so somebody's got to make some judgment calls about the sites related to what the exposures were, the quantity and the type of exposure, whether it was inhaled or skin or what have you. And that may be the job for the administrator and his staff.

DR. WARD: Tom?

DR. ALDRICH: I think you make a really good point about women being left out of much of the research that's gone on to generate the list, and mostly we're talking about breast, ovarian, uterine, cervical.

As far as ovarian they're probably going to wind up being included along with the asbestos risk. Breast seems to me to be the big problem. But aren't there enormous databases of breast cancer patients and wouldn't it be a quick, easy study to do a case-control study of breast cancer patients for World Trade Center exposure in the background? Wouldn't that be something that could be done from retrospective data that's already sitting in a database up at Sloan Kettering or somewhere?

DR. WARD: I doubt it.

DR. ALDRICH: Couldn't we marry that with our other research mandate to say you must do a case-control study?

DR. WARD: Well, I think it's an important issue but I don't know. I mean, it's usually epidemiologic studies are not, you know, there's no such thing as easy in epidemiologic studies.

DR. ALDRICH: True, but breast is such a common tumor that it might be one where this kind of approach would be very fruitful in a very short period of time.

DR. WARD: Right. And I do think that, you know, especially if we could do a population-based study rather than a hospital-based study, there might be some benefit. So okay, I think we need to figure out, I mean, I think there's concern about over-reliance on the IARC list. But, I mean, I'm not sure that it makes sense for us to recommend fine tuning the IARC list any further because I think we're going to run into the same problem we've run into before, that we don't have enough information about level of exposure and route of exposure and relevance to further refine that list. And in addition most sites will be listed -- will be on the list because of their association with many or at least a number of carcinogenic exposures, so their inclusion will rarely be based on one particular exposure. And even for benzo(a)pyrene, for example, benzo(a)pyrene is just one of many PAHs and a large number of -- or at least a significant number of the PAHs are carcinogenic. It's not just benzo(a)pyrene.

So I, I mean, so somebody else, I mean, could kind of, I'm looking at Steve 'cause he's been so good at pulling consensus together. Kind of summarize where you think we are from hearing the discussion, both what you think there's general agreement on and what there might not be general agreement on that we should discuss further.

DR. MARKOWITZ: So I gather there's some consensus around recommending the use of the IARC 1 and 2A categories in combination with the NIOSH list they've already published in their first report on carcinogens, the contaminants of potential concern, to identify specific organ sites where a cancer is likely to be related to World Trade Center exposures; and then secondly that that list be supplemented by additional cancer sites in which there's either a strong biological plausibility, strong exposure information or epidemiologic data that support addition of those sites; and third I would -- I'm not sure there's a consensus about this but that rare cancers should in addition be included, rare being defined by site or by age. Was there anything else?

DR. WARD: And I think the -- I mean, so two outstanding issues are, you know, we probably don't have to go further in defining rare, but I think we should acknowledge there is a big complexity there so, you know, I mean, is brain rare? When brain is rare -- and no, not rare. Okay.

DR. HARRISON: Liz, excuse me, I just want to say goodbye. I'm sorry but I have to really.

DR. WARD: Thank you so much. Sorry.

DR. HARRISON: And I do support what's being said.

DR. WARD: Okay, great. Great. Thank you. I'm noting to the record that Bob Harrison is leaving.

MS. HUGHES: Can I ask one point of clarification? Is there a list that talks about what the average age are for different cancers? 'Cause we haven't seen that table.

DR. WARD: There's actually lots of data and I can easily provide some of -- I mean, I can provide all of it basically from the work that we do at ACS. So we basically have age-specific incidence rates for pretty much every cancer and from that -- and we also have estimates of the number of people per year diagnosed with specific cancers at specific ages. Sometimes those numbers can be a little bit easier to digest. And these are not just our numbers, I mean, we share the numbers with the National Cancer Institute and the CDC, so that's pretty straightforward information to provide. I think what's more difficult is to know where to draw the line as to what we consider rare and common but I'm imagining that we won't get into that level of detail in our recommendations.

So the only issue -- one of the issues that I feel is not covered there and maybe we should at least address is, as Tom said, for breast cancer it, you know, I mean, we either could take no opinion or we could say it should be covered or we could say that it really needs to be a research priority because most of -- a lot of the data that we're basing our determination on is occupational studies where there were not sufficient women to address female, breast and gynocologic cancers.

DR. ALDRICH: Steve Cassidy just pointed out that the EMS fire department study is being analyzed as we speak and its results will be in the not too distant future and more than half the EMS workers are female. Now, the numbers won't be 10,000 but it'll be a lot.

DR. WARD: Great.

DR. ALDRICH: And breast is a common tumor, so.

DR. WARD: Great. And that fleetingly passed my mind, too, so I'm glad you mentioned it. But still for the recommendations at this point in time we have to decide whether to just let it rest or to make a specific comment about it, I think, just because it is one of the foremost common cancers in the population and we're really not able to address it with that particular database that we're relying on for most of our information. So even if we just say that, it should probably be addressed. In the context of whether the -- you know, why did we choose to take this approach and then what are the limitations of the approach. Steve?

DR. MARKOWITZ: I want to come back to Bill's point because I think it is a vulnerability for the administrator about adopting this approach, which is, you know, that list of 287 chemicals was, you know, contaminants of potential concern. I keep thinking about potential and thinking about what kind of exposure -- kind of sampling that was dependent upon and we heard about some of the limitations of sampling, and it may be that some of those exposures were not important at all or maybe even not have occurred at all. I don't know what potential means there. So it may be worth amending or putting in into the text around these recommendations that this list should be examined with reference to, you know, the validity; acknowledging that there are, you know, big problems with the measurements that were taken.

DR. WARD: Yeah, and I think one of the things that we presented yesterday was partly a selective view from me on, you know, what -- of the ones that are 1A, like asbestos, I kind of highlighted some of the ones where they were significant exposures so no one can argue that one percent by way of asbestos is not significant, and then they're also, you know, group 1A with very strong evidence of carcinogenicity and pretty strong evidence about specific sites, and some of the other ones that we focused -- that's one of the reasons we focused on the metals

because there were a number of metals that were there and a fair bit of -- and reasonably high concentrations that were group 1A, so I think when we look at it there will be some carcinogens listed that some might argue -- I mean, vinyl chloride is an example where I, at least, wondered you know, vinyl chloride is listed but was it really a significant exposure, but, you know, it would take deep digging to know that because, you know, if it was a product of pyrolysis of some of this stuff, then it might have been a significant exposure.

But yesterday I kind of focused on the ones where there was evidence both that there was -- the 1As where there was evidence of substantial exposure but it would be a lot of work, I think, to go through and try to look at the others.

And yeah, and it's probably a caution 'cause it's just based on evidence that it was there. There was no minimum set for the amount that was there. But I think that it's probably also true that many of the ones that were, you know, were facing a fair number of sites on, like asbestos, were there in large quantities, and that there were numerous lung carcinogens present. So it's really very few sites that will be based on, you know, one compound alone that had questionable exposure associated with it, I think.

Kimberly?

MS. FLYNN: I'm just wondering whether we need a special statement about children because children are not just little adults. I don't know if children cancer sites differ from adult cancer sites, and maybe Leo could speak to this.

DR. TRASANDE: Thank you. I think Steve's comments start to address this insofar as there are, if we -- and I think there's a delicate dance of how this is written that will -- we'll just have to keep a close eye on.

I think, I am -- I always have some caution about a blanket inclusion of all of the whole population without regard to any plausibility or scientific argument. But I think the argument that Steve has pointed out about the rare cancers for which there are potential benefits by including in a precautionary mode, that are real and important to consider, so my current inclination, and I think this needs to be a group process; I certainly shouldn't drive this, would be to include all pediatric cancer in the bill. But I say that with quite a bit of caution recognizing that there are a host of cancers that will occur naturally in an unexposed population. And that's a risk that we all -- I think we all are accepting across a host of other conditions as well.

DR. WARD: Julia.

DR. QUINT: I was just going to say that some of the uncertainty about the list of chemicals and which ones were relevant and some of the exposure route data is offset too by the large number of volatile chemicals for which, you know, we have

-- that are 2B carcinogens, a lot of them -- for which we have no human data so we won't be saying anything about the sites for those chemicals. So I think there's uncertainty on both ends where we're leaving some possible cancers out because we don't know -- we don't have the data, we don't have the studies to support them, and we'll overstate some other things maybe but there is -- and those qualifications have to be clearly stated in the document. I mean, we're still operating in an area of uncertainty; we're just doing the best we can based on the information we have.

DR. WARD: Right. I agree. And I think, you know, I mean, in some ways until we actually see the list and how it tabulates, we may still need some further discussion but it sounds like there's some agreement at least on the approach. So is there anyone who would still favor listing all cancers as opposed to the approach of trying to narrow down the focus somewhat by looking at the IARC or looking at the criteria that we've discussed, the IARC criteria, the nonmalignant irritation and inflammation, the epi studies, the rare cancers and the proposal to include all pediatric cancer? Valerie?

MS. DABAS: I guess my reasoning for saying all is because I haven't seen the list yet. You know, these are all lists that, you know, we're saying okay, well, the epi studies, biological plausibility; what does that mean? Which ones are they? Until I see it on a chart, then I can't say that I would definitely say okay, let's piecemeal it out because most -- 90 percent of the cancers are included, and there are 10 percent that we know for sure that will never be, you know, associated with exposure, that those are the ones that we're leaving out.

My concern is just, we won't have this list today. I'm assuming that once we leave here, you know, the list will go around. I'm not sure what the -- how we're going to take it from here but I mean, IARC plus this plus that. If I could see it, I think I might be able to have a better understanding of where we're going with this and not -- and move from all to that list. But until I can see that list, I can't move from all to this.

DR. WARD: Kimberly?

MS. FLYNN: Oh, I'm sorry.

DR. WARD: Oh, I'm sorry. Let's hear from Julia and then Paul suggested we have a break so that everybody can stretch and think.

DR. QUINT: I just have one -- do we have a list of all the cancers? I mean, even when we get the list of the ones we've mentioned, I'm not sure what universe that represents.

DR. WARD: Well, actually I mean, it's not all.

DR. QUINT: All cancers, I don't mean all cancers in the world. I mean, all cancers

that have been diagnosed or whatever that seem to be WTC-related. Because that's the denominator that we're --

MS. DABAS: I don't think we can 'cause while I sat here today I got an email from somebody that was diagnosed with sinus lymphoma, some type of sinus lymphoma, so every day I get a new call about somebody that is diagnosed -- has been diagnosed and hasn't come forward yet. Or, you know, lives in another state and is completely oblivious to the discussions that go on here or go on in New York City about cancer, and have convinced themselves, you know, that it's not related so therefore they shouldn't make a phone call to, to that.

And then again, you know, these monitoring programs are not monitoring for cancer so people are steered away from them. If you believe you have cancer, you're going to an oncologist, you're not going to Mt. Sinai. You know, once you've been diagnosed you're definitely not going to take four hours of your day to get the first exam and then follow-up exams because you're going from one oncologist to a PET scan to, you know, all these other appointments.

What I've been told by the people that are diagnosed is that they retired from the NYPD and became full-time patients as their second job. So in doing so reporting their cancer is never the first priority.

DR. WARD: But I think, yeah, there are lots of ways cancers are classified but the list we shared earlier -- so this is basically the classification by primary site and this is a standard classification and it should really capture all malignant neoplasms. There is going to be a category of other and unknown. There's other ways to classify cancer, by histology, but probably this would be the most logical way to classify cancer and it would capture all the histologies. Yeah, and then but the question of the rarity is you may be able -- a cancer may be rare based on its histology, not just its primary site and so we may have to grapple a little bit with that.

DR. ALDRICH: I think Dr. Harrison mentioned the premalignant conditions. I think it was -- and I think those are important, the hematologic premalignant conditions are important things to include in the coverage specifically because those people definitely need follow-up. They may not need expensive treatments, which is a good thing, but they definitely need follow-up and ought to be specifically included, even though they're not cancers. And maybe on the other end of the spectrum, of course, we wouldn't want to include basal cell carcinomas of the skin because it's really not the same kind of biology as other cancers.

DR. WARD: Yes, and I totally agree with you and I'm hoping -- well, so not only do I agree with you, and I think that opens the door to an important research area because I do think that, especially with multiple myeloma, there's a lot of new

research on the premalignant conditions, and so, but I would appreciate that one of the clinicians actually puts together a list of what those are because --

DR. ALDRICH: I nominate Dr. Rom for that.

DR. WARD: Good. I know some but I don't think we know all. Leo?

DR. TRASANDE: I just want to make a follow-up comment that, related to my comment in the earlier session about the possibility of adolescent and early adult cancers in pediatric or perinatally exposed populations for which we have no idea. I'm not saying for which we have no idea a priori as to which may occur. And I'm pointing this out as a potential research need more than anything else. I'm not suggesting it be included in the bill but I think it's certainly a concern that merits watching. It might be that early onset adult cancers arise in pediatric exposed populations insofar as there's greater proximity, greater time of exposure, acute subchronic and chronic types of exposures as well. Thank you.

DR. WARD: Okay, so I think we should take a break so everybody has a chance to move around and think about the issues.

(Recess 2:40 p.m. to 3:08 p.m.)

DR. WARD: So all the committee members take their seats. Hi, John and Virginia, are you still with us?

DR. DEMENT: This is John. I'm still here.

DR. WARD: Hey, John. Since we've been talking for a long time and I know you were able to interject once, I would like to give you the opportunity if there's anything you'd like to add to our discussions before we get in the thick of it again and forget you're there.

DR. DEMENT: No. I think I agree with the approach that we're taking. I'd like to hear a little more discussion of the rationale for including all of the pediatric cases, if that's the proposal on the table.

DR. WARD: Okay, it just happens that Leonardo's tent is up so we'll --

DR. DEMENT: Very good.

DR. TRASANDE: All right, I'll address John's question. The thought process flowed from the fact that we know that a number of members of the community, many members of the community had exposure ranges that likely overlapped with ranges seen in firefighters and other responders in which increases in cancer had been detected, and that raises the significant potential or plausibility. The fact remains that in a sample of at most 46,000 children below 14th Street on September 11, 2001, it's un -- it would be hard to be convinced by any study that would be negative for cancer associations, and accepting that as definitive. And in the absence of such a study, we have to fall back on biological plausibility and in the context of children's unique vulnerability to chemicals such as those identified

in the World Trade Center disaster, there remains an extra cause for caution and perhaps precaution in that population. And so I can't define for you a footprint of cancers that I would expect plausibly to be increased in a pediatric population because I don't think we've seen a pediatric population exposed to something of this magnitude. I suppose we could start to reason by certain disasters like (inaudible) but they're different.

And so that begins the line of reasoning towards supporting the inclusion of pediatric cancers, and it builds to some degree on the principle Steve outlined about including rare cancers. I think they're grounded in the fact that there's really not an epidemiologic platform on which to build and sustain a definitive decision, yea or nay, as to whether an association can be confirmed.

So John, clearly — love to hear your thoughts -- you're much more expert in the world of carcinogenesis than I am.

DR. WARD: John, do you have any comments?

DR. DEMENT: Yeah. Yeah, I agree with the concerns and somewhat the rationale. I guess what we're talking about is cancers that would be different from the sites that we're going to identify based on the identified pollutants in the exposure and the IARC list. So it would be those that would be again, fairly rare, I would think in addition to those.

DR. WARD: Okay.

DR. TRASANDE: John, and my response would be that given what little we know about the causes of cancer in adults and what much less we know about the causes of cancer in children though, benzene 1,3-butadiene and a few others coming to mind, I think it's hard to a priori elaborate such a footprint that we would anticipate for pediatric cancers that might emerge or a unique pattern. Other than some of the increases in incidents that we've seen in the context of increasing chemical exposures at large, thinking of testicular, brain and leukemia being the three that I can think of. But that wouldn't be a reason for putting those three conditions above all of the others in the context of an acute World Trade Center-related exposure. Those are in the context of more sub-chronic or chronic exposures.

DR. WARD: Yeah, and I guess the other issue is that just the distribution of cancer types in kids is so different from that in adults that you really can't -- I mean they don't even line up very well, like there's not much lung, there's not much colorectum, so yes, so it would be hard to infer one from the other.

Okay, and I mean, I do want to make sure, I think, I don't know that we'll have a -- be able to make, have a statement drafted to read to the committee by the end of this meeting unless anyone else has had time to write one. I hope to write one.

DR. TRASANDE: So my placard was up for a different reason.
DR. WARD: Oh, I'm sorry.
DR. TRASANDE: It was process, actually, related.
DR. WARD: Okay.
DR. TRASANDE: And so I would be keen to see a draft consensus document, if we could achieve a rough consensus here. And I would see the need for -- I don't think we're going to get there by 4:00 p.m., given that it's 3:15. And so my anticipation is that we will need a conference call follow-up to review and approve a draft document. And that brings me to well, how is that document going to be created, and my -- and I'm certainly not committing to be a major author in such a document. There are others that probably are best suited to do that but I do think we need to resolve pretty quickly what's next in getting to that report and then having a discussion about it, but that's just a suggestion on my part.
DR. WARD: Well, Dr. Howard has already granted our extension for our comments to be submitted no later than April 2nd so we've moved the deadline from the March 2nd to April 2nd. I think there's a couple of components, I mean, two things that I think we can do fairly quickly after this meeting is write up a summary that will include the list of IARC carcinogens in sites, so everybody has an opportunity to look at that, look at the other sites that we've agreed to based on the lines of evidence that we've discussed. Then I think there needs to be -- and I'd like to do that sooner rather than later just so people can think about it. But then there needs to be an effort to actually write our recommendations out in a report. We will hopefully fairly soon have access to Ray's transcript of our discussions this afternoon, which he's agreed to put first on his priority list above the rest of the meeting. So we will actually be able to pull some ideas and text from things, you know, thoughts that people have expressed during this meeting. And then of course if there are people who would like to work on a draft specifically, then we can have volunteers to do that as well. I'm certainly willing to work on it, too. But then the idea would be to get a draft out that then would be the topic of discussion at a conference call after -- hopefully we would get the draft out long enough before the discussion so that people would have an opportunity to review it in detail and possibly even send comments so that we could try to incorporate them in the draft that we're reviewing on the conference call, but that is a pretty tight time schedule. Now our conference call will have to be announced in the Federal Register so Paul can talk a little bit about that.
DR. MIDDENDORF: As far as the Federal Register is concerned, basically just give you the short story, I'll need to draft the Federal Register notice next week, early next week, so if anybody has any suggestions on agenda items, I need to get those

before early next week.
DR. WARD: Yes, Leo?
DR. TRASANDE: I also just have one other -- I realize that this -- the other at least burning topic on my forebrain about this meeting was the research agenda and whether we as a committee needed to approve that document from which the draft was sent around. And my instinct would be to try to close that aspect of business, that the conference call would focus on the cancer document.
DR. MIDDENDORF: I don't think we need to do anything more with the document, it has been submitted. If there are new research ideas that the committee wants to forward on, they can begin developing a new document.
DR. WARD: Glenn?
DR. TALASKA: I was wondering, one thing I mentioned this to you once, Liz, and to other members of the committee, one of my concerns is that, really, to honor the people that were the first responders in this site that we learn something from the mistakes of the exposure metrics that were gathered for this particular catastrophe, and perhaps is it within our purview to be able to make recommendations of what things should be included for a national response, for the next -- to protect anybody else in case there's another catastrophe of this magnitude or a magnitude like this? Is that something that this committee can deal with?
DR. WARD: Well, I mean, my first question which, and then I'll turn it over to Paul, is I think to a certain extent that has been done in other venues so my first question would be to look for whether it's been done before and et cetera, if we really have something to add, but I'll turn it over to Paul in terms of our charge.
DR. MIDDENDORF: Yeah, I think if you look in the Zadroga Act and looked at what the charge for this committee is, it is a scientific and technical advisory committee, and that would probably be outside the scope. However, if you wanted to make suggestions to the program on things on an individual basis, you're more than welcome to do that.
DR. WARD: Right, it's also possible that members of this committee, if there's, you know, if they feel moved to, to get together and write a paper, then, you know, they -- because we are going to be immersed in depth in some of these issues and there's certainly no prohibition from taking that into a scientific publication with people who would like to work together on that.
DR. TALASKA: Okay.
DR. MIDDENDORF: It would not be a product of the committee, though. That would be your individual efforts.
DR. WARD: Right. It would be a byproduct but not a product. So I'd like -- I mean,

is that process -- Valerie.

MS. DABAS: Yeah, I just had a question for Paul. Did you want us to send you possible dates or how would it work in trying to figure out? You said you needed some time to put it on the docket, so I just wanted to know if you had directions for the committee as far as what they need to do to facilitate that.

DR. MIDDENDORF: Yeah, what I'll do is as soon as I get back in the office I'll send a Doodle request and try to identify times. One of my questions for you: Do you think that a four-hour time frame is enough? I'm getting a lot of head shaking, so. We will have to include a public comment session so that would reduce it to about three and a half hours. But I think we can make that a short public comment section but we do need to allow that within our agenda. And it would probably be close to the end of March because that's the only time frame that's available to us in terms of when I have to get the Federal Register notice in and how much lead time I have to give them.

MS. DABAS: And if the Mt. Sinai or the fire department study is out by then on the EMS workers, would we be able to see those and evaluate those, and if anybody from those entities wanted to present the findings, would that be okay for that date?

DR. MIDDENDORF: It's certainly an agenda item you can suggest. And I'm wondering is that actually going to be published or it's only going to be submitted at this point?

UNIDENTIFIED SPEAKER: Yeah, it's going to be submitted.

DR. MIDDENDORF: And so I doubt that it will be out by -- in the next month.

DR. REISSMAN: I just wanted to respond briefly to the question about whether or not your advice or your input would be helpful. You know, we're always interested whether -- it's outside the committee, but we've done a lot at NIOSH, and also within HHS in general, in response to the lessons that were observed, I'll put it that way, in 9/11. And one of the major projects that NIOSH tried to help coordinate in all of this was an emergency responder health monitoring system, and it's a guidance document that's in a -- I think it's in a docket with NIOSH, and I'll find that and give it to you so that it can be put out there. But it talks about all the lessons learned in all of this from a responder safety and health perspective. Not from the community perspective 'cause NIOSH typically doesn't deal with the community except within this venue. So I just wanted to let you know about that.

DR. WARD: Are there comments or questions about the process? Glenn?

DR. TALASKA: No, no. That was -- sorry.

DR. WARD: Okay, so any other questions or comments about either the discussions today or the process? Yes.

MS. HUGHES: Can you clarify a little bit more how the report will address the precancerous conditions? 'Cause I know that had come up. That it wasn't only the end result but sometimes something along the way.

DR. WARD: Well, I think we specifically talked about the precancerous conditions for the hematologic cancers and the lymphomas, where there's a very known -- where many of them do progress to the full-blown cancer. I don't know if there's any consideration of any other kinds of premalignant conditions and I'm sure there is a reason to think about them.

DR. ALDRICH: I'm probably the wrong person to ask. I'm not familiar with any other areas where there are well-defined premalignant conditions that have a, you know, inexorable progression the way they do in hematology.

DR. WARD: Well, the one I can think of is colon cancer.

DR. ALDRICH: Yeah.

DR. WARD: So if you, if we screen people for colon cancer, we're going to remove adenomatous polyps that then will be -- so it's not completely a moot question. I don't know that we want to go too deeply into it but it's -- the other question in this is just, I guess I want to titillate people -- I mean, the other difficult question is down the road is lung CT for screening. Not that that would necessarily prevent a cancer but it could detect it early. And obviously it's not going to be a yes/no answer because it hasn't been studied in this population with all -- but, I mean, these issues are going to be important down the line and it's good to put them on the table. Yes, Julia.

DR. QUINT: I have a question. How would this differ from medical guidelines which in occupational health are often developed to help physicians diagnose and recognize, you know, the work-relatedness of disease? Would this be different than that or?

DR. WARD: It could be because for some of these things we're still -- I mean, well, for colon cancer for example, you know, there are guidelines for the general population but it's really a question -- but we have to acknowledge that in the course of screening, we will be identifying premalignant conditions that -- and so and treating them. So that's one area. For lung CT, I think the problem is there's only now just recently been a clinical trial demonstrating that screening high-risk people, by virtue of their smoking history, with lung CT, it is a benefit in terms of reducing mortality. There is, however, both a question of radiation exposure, they're screening yearly, and there's a question of morbidity associated with --

DR. MARKOWITZ: False positives.

DR. WARD: The false positives. So and what's different about this population is it's, you know, we don't know -- first of all, we don't have the same degree of

confidence in our estimate that it's of high-risk. We may have pulmonary abnormalities that could make the reading of the -- you know, so there's a million questions that would come up and it, you know, I guess it's a good way to end the meeting to know that we -- we're certainly not answering all the questions about cancer and treatment of cancer and screening and early detection of premalignant conditions in this meeting. And we can't possibly but they are serious questions. So other comments or? Steve?

DR. MARKOWITZ: I think, you know, Barrett's esophagus is another premalignant condition.

I want to go back to the issue of childhood cancer just for a moment. The logic in covering childhood cancer is that kids were -- some kids were substantially exposed, that the population's so small that we'll never get a epidemiologic answer from that population and that kids have unique vulnerabilities. So in the adult population where we have this enormous, you know, decades of research on, mostly or a lot epidemiologic demonstrating this causal relationship between exposures and the cancers, which we don't have in kids. So is there anything beyond those three things that we can point to that would bolster the case for kids having cancer being covered?

DR. WARD: I think maybe expanding a bit on the increased vulnerability and biologic plausibility because you have, you know, I mean, kids by their very nature have more dividing cells and I think there is a pretty strong line of argument about -- I mean, even the EPA, I think, sets their, you know, has just kind of sets risk limits for kids differently than for adults based on vulnerability so I think those things could be cited.

DR. TRASANDE: Just to expound on that a little bit, and when I made that initial round of comments this morning, I had left the traditional line of arguments, what I call traditional because I just have used them a lot early on in my career, but children's ventilation rates are greater per pound and therefore they inhale and they could have inhaled more out of proportion to their weight than adults in the context of the World Trade Center disaster.

Their lungs are in a developing phase all the way through age 20 and so a toxic injury could have more significant consequences at that time of life. And there are others as you mentioned developing organ systems that could fail or be deranged as a result of chemical injury. And then there's the longer latency over which they can have cancer occur, which is a nontrivial component of the arguments. I think that's just elaborating on; I don't think it's adding anything intrinsically new, but I think it provides cement to the foundation of the argument and the literature is substantial in those regards.

DR. WARD: So let me ask one question of Paul and the NIOSH folks, so when we -- let's say if we wanted to address the issue of childhood cancer, do you want the committee to come up with really a rationale that cites literature or do you want us to just, you know, essentially say what Leo said and not cite literature? What is your -- what kind of documentation are you requesting for these recommendations?

DR. MIDDENDORF: The recommendations can be whatever the committee chooses and they can choose to document the recommendation to the extent that they want. But I think the point is that the more the scientific basis there is for it, so if you go into the literature and you do literature citations, that makes your case stronger. But it's up to the committee as to how strongly they want to make that.

DR. WARD: Yes, Catherine.

MS. HUGHES: I just want to give some background information generally on children downtown, because there was that great program for responders, they first came out with the guidelines for adults and they revised them, and finally after many years, the pediatric guidelines were developed, so it was many years later. And so there's a huge catch-up game going on here. And there's not has been as much attention in both time or money in doing the studies, just because there is such a limited population.

DR. WARD: And has anyone made an estimate of what -- of the number of childhood cancers that might be expected in the 46,000 kids; I'm talking specifically now about childhood cancers, not cancers as they get older. Has that been done or not?

DR. TRASANDE: (Inaudible) matter of public record. Not to my knowledge. It's simply a calculation exercise derived on SEER data would really be my basis as a starting point.

DR. WARD: Well, it might be useful I guess in terms of writing up the recommendations. It might be useful as just one of the reference points. But I guess I mean, my sense is that we don't -- you know, we're not being commissioned to write a 50-page paper but I think, you know, I think we all know what some of the more difficult points are and I think the childhood cancers may be a little bit more debated, so maybe we should, you know, we should think as a committee then for those things that we think will need a higher level of defense or of explanation, that we do ask committee members who have unique expertise in those areas to pitch in and help to draft those sections.

And maybe we could think about having kind of the main document which summarizes the key recommendations and then kind of supplementary material

that has the more detailed reference information supporting the -- supporting our recommendation.

So would people like to volunteer at this point to help with the drafting of recommendations or to help with drafting specific parts of the recommendations?

DR. TRASANDE: I'll help with something.

DR. WARD: Great. And Leo, we're counting on you for childhood cancers.

DR. TRASANDE: I can certainly provide -- pull from multiple sources a summary of the key literature that one would want to cite.

DR. WARD: Good. So.

MS. FLYNN: I have another process question which is at what point would the rest of us get to see the draft so that we would be able to comment on the call or even before -- I mean, is there a possibility for a daft to be circulated before the call and comments from some of us who are not among the original drafters?

DR. WARD: I mean, that would be ideal and I guess what we need to do is work backwards from the date of the call and see what's feasible. I mean, my hope would be to get at least a one-page summary out to the committee next week. You know, really just trying to synthesize what our main points were and also to make the table of the cancer sites from the IARC, you know, from all the different sources so the committee has an early preview of those documents; and then to work on the more -- and to take feedback on that and then simultaneously work on the longer rationale document so that it can be distributed and it can be commented on before, you know, before the call so that the call would really be mostly to discuss the more difficult areas and make sure we have the language exactly the way we want it, but that's what we hope for in an ideal world. And we'll certainly do our best to achieve that.

DR. TALASKA: As much as I'm loathe to nominate another committee member, I would really love to see if John help us with the asbestos section.

DR. WARD: John, are you still there?

DR. DEMENT: Yes, I am. And yes, I'll help you with the asbestos section.

DR. WARD: Excellent.

DR. MIDDENDORF: Since we're talking a little bit about process and timing, we also need to be able to post whatever document it is you're going to be discussing on the conference call; it has to be posted several days ahead of time so that people who want to comment on it and provide comments in our meeting, have a chance to look at it so, you know, that backs it up even a little bit more.

DR. WARD: Okay. Valerie.

MS. DABAS: I know you talked about summarizing but I think, I know for me, one of the things that I do want to see is that list because we talked about biological

plausibility, we also talked about rare cancers and defining -- having definition for that and then the IARC list. So I think once we get those three things and the list, I think that would be great if we can circulate that first, just in case anybody had comments on it. I'm sure I will.

DR. WARD: Yeah, and that is the idea, to give out the most -- you know, to distribute the most important information first while we work on the details. So unless anyone else has a further comment or concern, I think we're ready to close the meeting. I appreciate all of -- yes, Steve.

DR. MARKOWITZ: This has nothing to do with cancer. We had one of the persons during the public comment, I think an air traffic controller, talk about being eligible for the World Trade Center health program for PTSD and it's a question whether our -- the charter for this committee includes a request from the administrator to advise on eligibility, and whether it's something that we should take up or are permitted to take up in the near future.

DR. MIDDENDORF: I can address that the Zadroga Act does require the administrator to consult on the eligibility for Shanksville and for the Pentagon but I'm not sure what it says -- Dori, do you know what it says as far as eligibility is concerned?

DR. REISSMAN: I think the question that the administrator can ask of the advisory committee is if there should be any modifications to the Pentagon and Shanksville eligibility criteria, but I don't think it goes as far as to say in the act stipulates, must present at the site, so that's a dilemma there. And I think she might address that directly.

MS. HOWELL: The administrator can ask for assistance with the initial Pentagon and Shanksville eligibility criteria, which is what you all had the presentation on yesterday. He can also, if he chooses, to open it up to modification of eligibility criteria for the New York responders and survivors. Then he would come to you all and ask for consultation there but he would have to initiate that process.

DR. WARD: So is there some mechanism by which the committee can transmit that particular issue to Dr. Howard? Can we just call attention to that issue for him in a separate communication?

MS. HOWELL: I mean, the program administrator takes notice of everything that happens during these committee members -- I'm sorry, meetings, and has been listening to all the public comments, so I mean, I think he's aware of the issue already.

MS. FLYNN: Can I just --

DR. WARD: Yes, Kimberly.

MS. FLYNN: I spoke to him at some length, and he applied for enrollment and was

denied, and he appealed the denial, and Dr. Howard denied the appeal. And so, I mean, you know, denied the appeal based on his geographic location.

Paul, I don't know what we can do but we really have to do something. I mean, even if we have to go back to the main authors of the bill. I mean, it is not in the spirit of the bill to exclude someone who truly fits the definition of a first responder on the day of 9/11. I don't mean to put you on the spot but I -- we have to make sure that this individual gets the care that he needs and deserves.

DR. MIDDENDORF: Yeah, I think it's something that we'll just have to look into to see what -- if anything can be done and if so what. I can't promise anything more than that at this point.

DR. WARD: Yes.

MR. CASSIDY: Just on that note on the post-traumatic stress, I know from speaking to Sheila Burnbaum that one of her concerns was literally anybody could claim that they have post-traumatic stress, and they have it from watching the event on TV, no matter where they were. And although I'm not an expert, you are. Maybe you want to comment on that. Is that crazy?

DR. NORTH: There are specific criteria in our diagnostic manual that talk about how you can get PTSD, what are the qualifying exposures and just seeing the news on TV is not one of those.

But it's beginning to sound to me like this is complex enough that it might be wise to want to discuss it further, and I, with my expertise, I think I can help us clarify some issues, but I don't think we have time now.

DR. WARD: Thank you. Yes, Tom.

DR. ALDRICH: There's a small precedent related to the New York State task force on -- worker protection task force, where we included a group of dispatchers.

MR. CASSIDY: Fire alarm dispatchers.

DR. ALDRICH: Fire alarm dispatchers who were not at the World Trade Center site but were taking calls all morning from people who were about to die and had subsequent -- some of them had some subsequent mental health issues.

DR. WARD: Thank you. Well, thank you all for your full and active participation. I think we've had a great and robust discussion, and I thank everyone from the community who hung in there for the long meeting. And John, thank you especially. I know it's really hard to stay on these calls long distance, and we really appreciate your input.

DR. DEMENT: Thanks a lot. I'm happy I could contribute to some extent.

DR. MIDDENDORF: Let me just express appreciation from the program for all of your thoughts and inputs. We very much appreciate it. Thank you.

(Meeting adjourned at 3:43 p.m.)

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WITNESS my hand and official seal this the 9th day of March, 2012.

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